

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,)
)
-----Plaintiff,)
) Case No.
vs.) 23-CV-975-RGA
)
LIQUIDIA TECHNOLOGIES, INC.,)
) Volume IV
-----Defendant.)

TRANSCRIPT OF BENCH TRIAL

BENCH TRIAL had before the Honorable Richard G.
Andrews, U.S.D.C.J., in Courtroom 6A on the 26th of
June, 2025.

APPEARANCES

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-and-

GOODWIN PROCTER LLP
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-and-

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(Appearances continued.)

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Counsel for Defendant

1 THE COURT: All right. Good morning. And I
2 believe we have -- Dr. Nathan, be seated -- Dr. Nathan on
3 the stand.

4 And, Mr. Davies, I guess you were going to
5 cross-examine him?

6 MR. DAVIES: I am, Your Honor. Thank you.

7 May I proceed, Your Honor?

8 THE COURT: Yes.

9 CROSS-EXAMINATION

10 BY MR. DAVIES:

11 Q. Good morning, Dr. Nathan.

12 A. Good morning.

13 Q. You don't dispute that Tyvaso was sold beginning in
14 2009; correct?

15 A. I do not.

16 Q. And it's just that in your opinion, prior to
17 April 2020, there was not an off-label sale of Tyvaso;
18 correct?

19 A. That's correct.

20 Q. So you're saying doctors did not write off-label
21 prescriptions of Tyvaso in PH-ILD; is that right?

22 A. I didn't say that.

23 Q. Okay. Yesterday you said prescriptions are
24 confidential, so you can't actually say what other
25 physicians wrote in their prescriptions; correct?

1 A. That's correct.

2 Q. And it's your opinion that prior to April 2020,
3 doctors could not write off-label prescriptions for Tyvaso
4 because they couldn't have intended to improve exercise
5 capacity without the results of the INCREASE trial; is that
6 correct?

7 A. That's correct.

8 Q. And so your prior sale opinions, you believe that it
9 has to be UTC that directly makes those sales; right?

10 A. Yes.

11 Q. And in your opinion, the prior sale -- and in your
12 analysis, that prior sale had to be a public prior sale;
13 correct?

14 A. Yes.

15 Q. Okay. You heard testimony about Dr. Rothblatt's
16 statements to investors that insurance companies paid for
17 Tyvaso for PH-ILD patients off label; correct?

18 A. Yes.

19 Q. But you don't believe Dr. Rothblatt's statements;
20 right?

21 A. I believe that's what Dr. Rothblatt said.

22 Q. But that didn't impact your opinion that there were
23 no prior off-label sales of Tyvaso for PH-ILD prior to
24 April 2020 that were reimbursed by insurance companies;
25 right?

1 A. The sales were for PAH, and how the physician used it
2 was at the discretion of the physician.

3 Q. You didn't review any sales records in this case, did
4 you?

5 A. I don't know.

6 Q. So you don't know what the sales were made for;
7 correct?

8 A. I do know they were made for PAH because in order to
9 get PAH paid for, physicians have to attest on the form that
10 the patients have pulmonary arterial hypertension.

11 Q. You heard Dr. Hill and Dr. Saggar say that insurance
12 companies rejected their prescriptions for Tyvaso when they
13 wrote them for PH-ILD; correct?

14 A. I heard Dr. Hill say that, yeah.

15 Q. Okay. And you heard that in some cases they were
16 rejected even when they checked the box for diagnosing with
17 PAH; correct?

18 A. I did.

19 Q. But you still believe that Tyvaso was never sold to a
20 patient for PH-ILD before April of 2020; correct?

21 A. Yes.

22 Q. In terms of how you treated the claims in your
23 opinions on obviousness, you believe that the '327 patent
24 claims would only be met if a physician knew that Tyvaso
25 actually produced an improvement in exercise capacity in

1 that PH-ILD patient; correct?

2 A. Correct.

3 Q. And it's your opinion, also in the context of your
4 obviousness opinions, that a physician could not have known
5 what Tyvaso would do in a PH-ILD patient before the results
6 of the INCREASE study were unblinded; right?

7 A. That's correct.

8 Q. Okay. I'd like to talk a little bit about dry
9 powders.

10 You talked yesterday that nobody would know how
11 to make a dry powder formulation of treprostinil; right?

12 A. A POSA would not know how to do that; correct.

13 MR. DAVIES: Can we look at the '327 patent.
14 And can we look at column 21, lines 6 through 14.

15 BY MR. DAVIES:

16 Q. And you see here, Doctor, that this portion of the
17 '327 patent identifies both dry powder and a dry powder
18 inhaler, composition of treprostinil; correct?

19 A. Yes.

20 Q. It says that these formulations were already
21 disclosed in 20- -- in the W0/2019/237028 publication;
22 correct?

23 A. I'm not sure which publication that is.

24 Q. But you see that it says that these prior art dry
25 powder inhalers and dry powder compositions of treprostinil

1 were already disclosed in W0/2019/237028; correct?

2 A. I see that.

3 MR. DAVIES: Can we go to column --

4 THE COURT: Sorry, Mr. Davies.

5 MR. DAVIES: Yes.

6 THE COURT: So when you said a POSA wouldn't
7 know how to make a dry powder formulation, is that because
8 the POSA you're thinking about is a medical doctor?

9 THE WITNESS: Yes.

10 THE COURT: So if the medical doctor was working
11 with a doctor of pharmacy, do you have an opinion as to
12 whether a doctor of pharmacy would know how to do this?

13 THE WITNESS: I really don't think so. I think
14 it takes a whole team to develop a dry powder inhaler. So
15 this wouldn't be a pharmacist by themselves in terms of
16 formulating the molecule and then coming up with a device to
17 deliver that, the dry powder. So it really takes a team.

18 THE COURT: All right. Thank you.

19 MR. DAVIES: Can we go -- stay in the '327
20 patent, and can we go to column 15, lines 1 to 10.

21 BY MR. DAVIES:

22 Q. And do you see here, Doctor, this is another
23 discussion in the specification of the '327 patent about
24 treprostini1 dry powder compositions and inhalable
25 compositions? Do you see that?

1 A. Yes.

2 Q. Okay. And here it says that those compositions were
3 previously described in U.S. Patent Number 9,339,507;
4 correct?

5 A. It says that, yes.

6 MR. DAVIES: Okay. Rob, can we go to the '793
7 patent and look at the related application data.

8 BY MR. DAVIES:

9 Q. And, Doctor, you offered opinions of -- sorry.

10 MR. JACKSON: The DTX number?

11 MR. DAVIES: DTX 2.

12 BY MR. DAVIES:

13 Q. And, Doctor, you offered opinions about the '793
14 patent in this case; correct?

15 A. I did.

16 Q. And if we look at the U.S. application data --

17 MR. DAVIES: Rob, can you blow that up. And you
18 can see the U.S. Patent Number 9,339,507 that's cited there.
19 Can you highlight that, Rob? It's about six lines down on
20 the left. Yep.

21 BY MR. DAVIES:

22 Q. And so you see that the '507 patent is actually in
23 the same patent family as the '793 patent and cited on the
24 face of the '793 patent; correct?

25 A. I see it's cited there.

1 Q. You're just not sure if it's in the same family
2 because you're not an attorney; right?

3 A. Yeah, I haven't seen that patent and so I'm not sure
4 what's in that patent.

5 Q. Totally understood.

6 MR. DAVIES: Can we look at back at the '327
7 patent. And let's look at column 20, lines 48 to 57.

8 BY MR. DAVIES:

9 Q. And this is another disclosure in the '327 patent
10 that's concerning dry powder compositions of treprostinil
11 and dry powder inhalers using treprostinil; correct?

12 A. I'm just reading it.

13 Q. Yeah, no problem.

14 A. Yeah.

15 Q. And do you see here that both the '507 patent that
16 we've already looked at and also the '793 patent that you've
17 offered opinions on in this case are both cited and
18 incorporated here by reference for that description of dry
19 powder inhalers and dry powder compositions of treprostinil;
20 correct?

21 A. You said that I looked at the '507 patent. I haven't
22 seen that patent.

23 Q. I'm sorry.

24 You looked at the '793 patent; right?

25 A. Correct.

1 Q. But you believe at least here in the '327, both of
2 those, it says they're being incorporated herein in their
3 entirety for the disclosure of dry powder inhalers and dry
4 powder compositions of treprostinil; correct?

5 A. Correct.

6 MR. DAVIES: Rob, can we please pull up DTX 62.

7 BY MR. DAVIES:

8 Q. And, Dr. Nathan, we've just been talking about the
9 '507 patent.

10 And you can see this is U.S. Patent Number
11 9,339,507 issued by the United States Patent Office;
12 correct?

13 A. I see that, yes.

14 Q. And the date of this patent is May 17, 2016?

15 A. Correct.

16 MR. DAVIES: Your Honor, I request that DTX 62
17 be moved into evidence.

18 MR. JACKSON: Your Honor, we object. The
19 witness has twice said he has never seen this patent before.
20 It can be used for impeachment or whatever he wants for
21 impeachment, but there's no basis to get it in through this
22 witness.

23 THE COURT: Well --

24 MR. JACKSON: And can I explain why, Your Honor?

25 THE COURT: Okay. Go ahead.

1 MR. JACKSON: So yesterday we filed a motion for
2 52(c) that they had failed to provide any support for their
3 idea that the '793 was prior art. What this is, is an
4 attempt to replace that, to get this other patent into
5 evidence on that to replace what they have done their whole
6 case and find an alternative to the '793 that is earlier in
7 the family.

8 They're trying to -- this is a backdoor way to
9 come up with a justification for what their prior art is.

10 THE COURT: Is this, Mr. Davies, on the list of
11 exhibits that you have for this case?

12 MR. DAVIES: It is, Your Honor. It's DTX 62.

13 THE COURT: All right. Yeah, that's right.

14 Well, so I'm going to admit it because there was
15 no doubt that it actually is what he says it is, and, you
16 know, Dr. Nathan can be cross-examined about it. And if I
17 made a mistake here, you can tell me about it later. Okay?

18 (Thereupon, Defendant's Exhibit DTX 62 was
19 admitted.)

20 MR. JACKSON: Okay.

21 MR. DAVIES: Thank you, Your Honor.

22 May I proceed?

23 THE COURT: Yes.

24 MR. DAVIES: Thank you.

25 BY MR. DAVIES:

1 Q. You testified yesterday as a part of your obviousness
2 arguments that a POSA would not have a reasonable
3 expectation of success with respect to Claim 14 of the '327
4 patent because a POSA would not be able to formulate a dry
5 powder treprostinil based on the '793 patent; correct?

6 A. That's correct.

7 Q. And that's the understanding that you applied in your
8 obviousness opinions with respect to Claim 14; correct?

9 A. That's correct.

10 Q. You agree that a dry powder inhaler was never tested
11 in the INCREASE trial; right?

12 A. That's correct.

13 Q. And you understand that Tyvaso DPI was actually
14 approved for treatment of PH-ILD based on results from the
15 INCREASE trial using nebulized Tyvaso; correct?

16 A. That's correct.

17 Q. UTC didn't run any additional efficacy trials using
18 their dry powder inhaler to secure an indication for that
19 dry powder inhaler in PH-ILD; right?

20 A. That's correct.

21 Q. You mentioned -- I'll just touch on this briefly.

22 You mentioned the ACTIVE study yesterday.

23 Do you recall that?

24 A. I do.

25 Q. And I think you called it the closest study to

1 treprostinil; is that right?

2 A. That's correct.

3 Q. Iloprost is, obviously, a different molecule than
4 treprostinil; right?

5 A. That's correct.

6 Q. And it has different pharmacokinetics and other
7 properties that are different than treprostinil; correct?

8 A. Correct.

9 Q. For example, it has a shorter half-life than
10 treprostinil?

11 A. Correct.

12 Q. You need to dose it more often than treprostinil?

13 A. Yes.

14 Q. And the actual formulation of the commercial product
15 is very different from Tyvaso; correct?

16 A. It is different.

17 MR. DAVIES: Can we go to Faria-Urbina, which is
18 DTX 348.

19 BY MR. DAVIES:

20 Q. And yesterday you spent some time talking with your
21 counsel about Faria-Urbina; right?

22 A. Correct.

23 Q. And I think it's your opinion that -- I think you
24 said Faria-Urbina was, at best, hypothesis-generating; is
25 that correct?

1 A. That's correct.

2 Q. But you agree that the dosing that's described in
3 Faria-Urbina was the same as the Tyvaso dosing that was used
4 at the time; right?

5 A. Correct.

6 Q. And you agree that that dosing is also within the
7 scope of the '327 patent Claim 1; right?

8 A. Correct.

9 Q. But it's your opinion that Faria-Urbina does not
10 include PH-ILD patients; is that right?

11 A. I think that there's evidence that many of these
12 patients would be categorized as pulmonary arterial
13 hypertension and not PH-ILD.

14 Q. Is it fair to say that you really can't tell one way
15 or another whether they didn't have PH-ILD because you're
16 doing a retrospective rediagnosis, which is the same thing
17 you criticized Dr. Waxman for?

18 A. That would be correct, yeah.

19 Q. Okay. Yesterday, counsel took you to the methods
20 sections and you said that to properly diagnose PH-ILD, you
21 would need CT scans and you couldn't do that in a
22 retrospective context; right?

23 A. I said that you need to scrutinize the CT scan. You
24 can do that in a retrospective context provided you look at
25 a CT scan, ideally in the context of a multidisciplinary

1 discussion with a pulmonologist and a thoracic radiologist
2 as recommended by our governing bodies.

3 Q. And if you look at what's provided on the screen
4 here, it indicates that for these patients, Dr. Waxman's
5 group reviewed the charts to identify patients with lung
6 disease based on both a pulmonary function test and a
7 high-resolution computed tomography scan of the lungs;
8 correct?

9 A. I see that, yes.

10 Q. And that's exactly the evidence that you said
11 yesterday that a POSA or a physician in this field would
12 need to accurately diagnose a PH-ILD patient; right?

13 A. No, that's not what I said.

14 Q. Okay.

15 A. They don't specifically say that they looked at the
16 CT scans themselves. They don't say they looked at it in
17 conjunction with a thoracic radiologist. And based on this,
18 they could have easily gone back and read a report from any
19 radiologist who might not necessarily have expertise in
20 interstitial lung disease.

21 Q. They say they reviewed these patients though;
22 correct?

23 A. They say to identify patients with lung disease based
24 on PFTs and HRCT scans of lungs.

25 But once again, they don't say that they

1 reviewed the CT scans or the reports of the CT scans.

2 THE COURT: And while Mr. Davies is thinking
3 here.

4 MR. DAVIES: Yep.

5 THE COURT: Those are the right sorts of medical
6 tests to have. Your point is maybe the right people weren't
7 reviewing them?

8 THE WITNESS: Correct. I've seen many reports
9 of CTs from radiologists without expertise. And then I look
10 at the CTs myself, and they're totally off base.

11 So -- and really to validate that they have ILD,
12 you have to look at the CT yourself. I mentioned yesterday
13 the entity of interstitial lung abnormality --

14 THE COURT: Right, I don't think you need to
15 repeat that.

16 THE WITNESS: Okay.

17 MR. DAVIES: Can we highlight on the bottom
18 column there the -- looking at the ILD, presence of
19 fibrosis. Do you see that, Rob? Go back. Nope. There we
20 go. Keep going.

21 BY MR. DAVIES:

22 Q. So it says: "An ILD or presence of fibrosis defined
23 as reticular septal thickening associated with architectural
24 distortion with traction" -- I'm going to say this one
25 wrong -- "bronchiectasis or honeycombing on HRCT."

1 Do you see that?

2 A. I do.

3 Q. And doesn't that indicate that Dr. Waxman's group
4 would have reviewed this data in diagnosing these patients?

5 A. No. Once again, they don't state that they reviewed
6 the CTs themselves, they just say what's there. And it
7 could have been a report.

8 Sometimes when you do a retrospective analysis,
9 it's very difficult to extract the CTs and look at the CTs
10 yourself. That's one of the issues with retrospective
11 analyses.

12 Q. You understand that these are actually patients that
13 were being followed by Dr. Waxman's group at Brigham;
14 correct?

15 A. They had been followed at Brigham, is my
16 understanding.

17 Q. So if anyone would have access to that information,
18 it would be Dr. Waxman's group; correct?

19 A. You would think that they would, but sometimes, even
20 at my own institution, all we have are reports of CTs
21 without actually having CTs.

22 MR. DAVIES: Can we please go to DTX 505. And
23 let's look at Table S1.

24 BY MR. DAVIES:

25 Q. And, Dr. Nathan, yesterday you testified about

1 Table S1 in Faria-Urbina, and I think you said that when
2 looking at this table, a POSA would be skeptical whether
3 these patients had PH that was caused at least in part due
4 to their interstitial lung disease because "this hemodynamic
5 profile looks more like a PAH-type phenotype."

6 Do you recall saying that?

7 A. I did say that, yes.

8 Q. And you pointed to two specific patients yesterday,
9 Patient 2 and Patient 3. And I'd like to look first at
10 their mPAP. It should be 54 and 58.

11 And you said with respect to those two values
12 for those two patients, that in your opinion, those patients
13 were more likely to have Group 1 PAH, given those values;
14 right?

15 A. That's correct.

16 Q. And you also looked at the PVR values, where are at
17 the very bottom row there. And you pointed to the values of
18 8.9 for Patient 2 and 15.2 for Patient 3.

19 Do you see that?

20 A. I do.

21 Q. And, again, I think what you said yesterday was,
22 again, that meant that these patients were PAH and not
23 PH-ILD because you've never seen a PH-ILD patient with a PVR
24 of 15.2 that was alive.

25 A. I did state that, yes.

1 MR. DAVIES: Okay. Can we go to Table 7 of the
2 '327 patent.

3 BY MR. DAVIES:

4 Q. Table 7, again, is the baseline patient data from the
5 INCREASE trial; right?

6 A. Yes.

7 Q. And you can see that the patient population in the
8 INCREASE trial actually included PH-ILD patients that had an
9 mPAP of 74?

10 A. Correct.

11 Q. Correct. And that's higher than the values you
12 pointed to in Faria-Urbina supplemental Table 1; correct?

13 A. Correct.

14 MR. DAVIES: And those -- if you look at the PVR
15 values as well. Can we highlight the PVR. Great.

16 BY MR. DAVIES:

17 Q. And for the PVR value, it -- the INCREASE study
18 included PH-ILD patients with PVRs up to 18.05; right?

19 A. Correct.

20 Q. And in your opinion, you've never seen a PH-ILD
21 patient with a PVR of more than 15.2 that wasn't dead;
22 right?

23 A. That's been my experience, yes.

24 Q. Okay. But these patients were nonetheless enrolled
25 in the INCREASE study; correct?

1 A. Correct.

2 THE COURT: Just for my edification.

3 For example, the 3.06 to 18.05 there, that's the
4 minimum and maximum of the group?

5 THE WITNESS: That's correct.

6 THE COURT: Thank you.

7 THE WITNESS: There's more to this, though. If
8 I may expand?

9 MR. DAVIES: I -- your counsel can draw that
10 out. Dr. Nathan has a chance to --

11 THE COURT: I'll tell you what. Why don't you
12 expand and I'll charge this time to the plaintiff.

13 THE WITNESS: Very good. Okay.

14 There were a number of patients who enrolled in
15 INCREASE with hemodynamics like that, and we had a number of
16 deaths very early on in INCREASE, within the first week or
17 two. There's a very good chance that these were the
18 patients who died as soon as they got into the clinical
19 trial.

20 Now, if you go back to the Faria paper and those
21 two patients, their hemodynamics --

22 THE COURT: Well, let's go back.

23 MR. DAVIES: Go ahead. Rob, can you go back to
24 Faria-Urbina.

25 THE WITNESS: What's important is not only their

1 baseline, but their follow-up. So let's look at Patient 3
2 who started out with a PVR of 15.2. And then at
3 follow-up -- and I'm not sure what the time period is -- the
4 PVR had come down to 3.3.

5 That does not happen in PH-ILD. When you're
6 talking about PH-ILD, you're talking about fibrosis of the
7 lungs, fibrosis around the vessels. No pulmonary
8 vasodilator is going to reverse that to cause a decrease in
9 the PVR from 13.2 to 3.3.

10 To me, that bespeaks very much so that this is
11 clearly a PAH patient just by virtue of that response we see
12 there. And this patient was alive for whatever length of
13 time versus the patients in INCREASE who likely died early
14 on.

15 THE COURT: Okay. You can stop there, Doctor.

16 The time goes to the plaintiff.

17 Go ahead, Mr. Davies.

18 MR. DAVIES: Understood, Your Honor.

19 BY MR. DAVIES:

20 Q. You understand, though, Dr. Nathan, that these
21 patients in Faria-Urbina would have been on treatment;
22 correct?

23 A. Yes, correct, they were on treatment.

24 And actually, another point that didn't come up
25 is that some of them were on treatments in addition to

1 inhaled treprostinil. They came in on other therapies as
2 well, so how much of the so-called response can be
3 attributed to inhaled treprostinil versus other drugs
4 they're already on is uncertain.

5 MR. DAVIES: Can we go back to the '327. We can
6 take this down, Rob, and let's go to column 26 of the '327
7 patent.

8 BY MR. DAVIES:

9 Q. And, Dr. Nathan, it's your opinion that the claims of
10 the '327 patent are based on the results of the INCREASE
11 trial; right?

12 A. Correct.

13 Q. And if we go to Example 3 in the '327 patent, you
14 agree that there's a description of the INCREASE trial that
15 starts here in Example 3; right?

16 A. Yes.

17 Q. And we've already looked at Table 7, which is part of
18 Example 3, and that includes the baseline patient
19 characteristics for INCREASE; right?

20 A. Yes.

21 MR. DAVIES: And if we go to Table 5, which is
22 column 32 of the '327 patent. And, again, still on
23 Example 3.

24 BY MR. DAVIES:

25 Q. Table 5 provides the summary of primary and secondary

1 endpoints in the INCREASE trial; right?

2 A. Correct.

3 Q. And in the '327 patent, Example 3, including Table 5
4 that we're looking at now, that provides the six-minute walk
5 distance results from the INCREASE trial; right?

6 A. Correct.

7 MR. DAVIES: Can we bring up DTX 375.

8 BY MR. DAVIES:

9 Q. And DTX 375 is a provisional patent application.

10 Do you see that, Doctor?

11 A. I see that, yeah.

12 Q. And it was issued -- well, filed in the United States
13 Patent and Trademark Office.

14 Do you see that at the top?

15 A. I do.

16 Q. Titled "Treatment For Interstitial Lung Disease"?

17 A. Yes.

18 Q. And that's the same title as the '327 patent?

19 A. You'll have to go to the '327 patent, which I think
20 is more specific for PH-ILD. This says treatment for
21 interstitial lung disease.

22 MR. DAVIES: Can we actually bring up the title
23 of the '327 patent.

24 BY MR. DAVIES:

25 Q. And what's the title of the '327 patent?

1 A. It does say the "Treatment For Interstitial Lung
2 Disease."

3 Q. The same title; right?

4 A. Correct.

5 MR. DAVIES: Can we go back to DTX 375.

6 BY MR. DAVIES:

7 Q. And you see that this was filed on April 17, 2020?

8 A. Yes, I do.

9 MR. DAVIES: Rob, can we go to -- it's DTX --
10 page 49 of DTX 375.

11 BY MR. DAVIES:

12 Q. And this is application number 63011810; correct?

13 A. Correct.

14 Q. And it was received April 17, 2020?

15 A. Correct.

16 Q. And this is a copy of the '810 provisional
17 application that you mentioned in your opening expert report
18 on infringement for the '327 patent; correct?

19 A. I believe that's correct.

20 MR. DAVIES: Your Honor, we request that DTX 375
21 be admitted into evidence.

22 MR. JACKSON: Your Honor, I don't think it's
23 proper. I believe it was cancelled as of the priority date.
24 Give me a second.

25 Sorry. I don't think it's relevant, Your Honor.

1 They conceded the priority date, and so I don't think this
2 is any longer --

3 THE COURT: What is the point here, Dr. Davies?

4 MR. DAVIES: It's the priority application for
5 the patent, Your Honor.

6 THE COURT: Right. But the priority date is not
7 in dispute, so what is the relevance?

8 MR. DAVIES: Your Honor, we believe that they
9 bear the burden on priority. We don't believe that they
10 have shown that so we think it is an issue.

11 THE COURT: I thought it was stipulated.

12 MR. SUKDUANG: Your Honor, I'm sorry, it was not
13 stipulated. And the pretrial order makes clear, and this
14 goes to Mr. Jackson's point, in the pretrial order,
15 paragraph 15, plaintiff takes the position that if -- we
16 believe the '793 patent is prior art.

17 Plaintiffs argue that if we present prior art
18 that's after the filing date, they bear the burden of
19 evidence on proving priority. They contend -- they have now
20 contended, and this is paragraph 15 --

21 THE COURT: Wait, exhibit -- Mr. Sukduang, I
22 remember at pretrial conference, I believe, the parties told
23 me the priority date was not in dispute.

24 MR. SUKDUANG: I don't think we -- I could be
25 wrong, Your Honor. It wasn't in dispute because they didn't

1 raise this issue. And now --

2 THE COURT: You can't say it is not -- so that's
3 a different thing if you say -- if you're saying they are
4 now raising an issue that is not properly raised, then the
5 response is it's not properly raised, not our stipulations
6 are off.

7 MR. SUKDUANG: I don't think we conceded on
8 priority. We have the record, and if we did, then the
9 record says what it does.

10 They also -- this is an issue that's not
11 properly raised. The '793 patent is admitted prior art in
12 the specification of the '327 patent. This issue, the
13 priority application, goes to the issue of the evidence
14 Dr. Nathan talks about in terms of Example 3.

15 THE COURT: So whatever it is that they filed
16 the motion about last night, that's locked into place as of
17 the close of their case.

18 MR. SUKDUANG: Yes, it's locked in their case.

19 THE COURT: So if they have a good point, then
20 it's too late to do something about it now. If they don't
21 have a good point, then you don't need it.

22 MR. SUKDUANG: They don't have a good point, but
23 the issue is -- this issue, this priority application, also
24 goes to the issue of the evidence that Dr. Nathan points to.

25 Dr. Nathan points to you need this Phase 3

1 clinical trial to know -- for obviousness, for all these
2 issues. And then he --

3 THE COURT: So if you're offering it for some
4 limited purpose relating to Dr. Nathan's testimony -- and
5 what is that limited purpose? That he is using art that is
6 subsequent to April 17th?

7 MR. SUKDUANG: No. Dr. Nathan is not using any
8 art. He is the plaintiff's side. He's arguing --

9 THE COURT: He's talking about art.

10 MR. SUKDUANG: He's talking about the INCREASE
11 study, which is Example 3 of the '327 patent.

12 That's not in the priority application. There's
13 no data from the INCREASE study in the priority application,
14 which is the basis that he says you cannot know anything
15 about these results unless you have the results.

16 That goes to this issue. Mr. Davies will take
17 him and show him where the examples end and where the
18 examples start. And Example 3 and 4 and 5 aren't there.

19 THE COURT: This is the provisional application
20 for the patent-in-suit; right?

21 MR. SUKDUANG: Yes, which he relied on and he
22 said he considered and it's on the exhibit list --

23 THE COURT: No, no. I agree with all that. I'm
24 trying to get -- the objection was it's irrelevant and so
25 that's what I was trying to get at, is it is relevant to

1 what? What are you trying to prove by offering it?

2 MR. SUKDUANG: It's relevant to the issue of
3 whether you actually need the data Dr. Nathan says you need
4 to file a patent application.

5 THE COURT: Okay. All right. So why isn't that
6 a relevant point? I mean, I know why it's relevant. But
7 why it's offered to prove that -- having something to do
8 with the need for data, why is that possibly -- why
9 shouldn't I admit it for that purpose?

10 In other words, what I understood them to be
11 saying is they're not arguing about the priority date.
12 They're arguing about what was in the provisional
13 applications, whether that was -- shows that you don't need
14 data, which is maybe their obviousness argument.

15 MR. JACKSON: Well, I actually think that is
16 arguing about the priority date because they're
17 saying certain things are in the --

18 THE COURT: All right. So why don't we do this.
19 I'm going to let them admit it for cross-examining
20 Dr. Nathan about it.

21 As far as I'm concerned, I have a distinct
22 memory that you've said -- you've both said, in other words,
23 you're not disagreeing with this, that the priority date is
24 not in dispute.

25 And we've tried this case for three days and

1 everyone agrees as to what the priority date is, so I don't
2 think it's in dispute.

3 MR. JACKSON: Yes. And just so the Court is
4 aware, I said it in the transcript on page 9, lines 7 and 8.
5 I explicitly said the priority date is no longer in dispute.
6 So he said that was what was discussed at the final
7 pretrial.

8 MR. SUKDUANG: That was not discussed at the
9 final pretrial. Mr. Jackson said that.

10 THE COURT: Well, he said that and you were
11 sitting there. And if he was not saying what was correct,
12 that was the time you say no. So I think it's resolved.

13 And I think the behavior -- and behavior is not
14 the right word. I think the conduct in the trial to date on
15 this shows that it's resolved.

16 So I'm going to admit it for whatever purposes
17 Mr. Davies can make here, but it's not going to change the
18 priority date.

19 (Thereupon, Defendant's Exhibit DTX 375 was
20 admitted.)

21 MR. JACKSON: Thank you, Your Honor.

22 MR. DAVIES: May I proceed, Your Honor?

23 THE COURT: Yes.

24 MR. DAVIES: Can we go to DTX page 30, please,
25 Rob.

1 BY MR. DAVIES:

2 Q. And on DTX page 30, Dr. Nathan, you can see
3 Example 2?

4 A. I can see it.

5 Q. And that's the same Example 2 from the '327 patent?

6 A. I'm not sure if it is or not. I'd have to compare
7 this to the final patent.

8 Q. Sure.

9 MR. DAVIES: Can we go to the next page for the
10 application, Rob.

11 BY MR. DAVIES:

12 Q. And you can see that there's no additional examples
13 in this application; correct?

14 A. Is this the next page following on that?

15 Q. Yeah. Let's go to the next page. And you can see --
16 let's go to page 32. And you can see it goes to claims
17 after that.

18 Do you see that, Doctor?

19 A. Yes.

20 Q. So this provisional patent application does not
21 contain Example 3 that we've been looking at that has the
22 data from the INCREASE trial; correct?

23 A. I probably have to relook at the whole document to
24 make sure about that, but if you tell me that, then I'll
25 take your word for it.

1 THE COURT: And it's in evidence so it's subject
2 to absolute determination later on. Maybe Dr. Nathan
3 doesn't know it off the top of his head.

4 MR. DAVIES: Absolutely, Your Honor.

5 Can we please go to the 2017 INCREASE protocol,
6 which is DTX 8. Go to page 10.

7 BY MR. DAVIES:

8 Q. And you were looking at the arms and interventions
9 yesterday with counsel?

10 A. Yes, I was.

11 Q. And you were asked about the starting dose of inhaled
12 treprostinil in the 2017 protocol; right?

13 A. Correct.

14 Q. And I think your opinion was there was no starting
15 dose; is that correct?

16 A. I think the inference from the insert when it says
17 approximately 6 micrograms per breath, without saying it, I
18 would read into that just one breath four times a day
19 although it doesn't explicitly just say that.

20 Q. It says the other name for the inhaled treprostinil
21 is Tyvaso; right?

22 A. Correct.

23 Q. And the dosing for Tyvaso at the time -- the starting
24 dose for Tyvaso at the time of the 2017 protocol was a
25 starting dose of three breaths; correct?

1 A. This is a new protocol. It's not necessarily
2 following the label of the 2009 label. So it doesn't say.

3 Q. That's fine, Doctor, but you agree with me that
4 Tyvaso was commercially approved and available at that time
5 with a starting dose of three breaths; correct?

6 A. You'd have to go to the label to show me.

7 Q. You don't remember what the starting dose is for
8 Tyvaso?

9 A. I'd want to see it to be sure that I'm answering
10 correctly.

11 MR. DAVIES: Okay. Let's go to the 2009 Tyvaso
12 label, DTX 357, page 3. And blow up the dosing.

13 BY MR. DAVIES:

14 Q. Do you see the initial dosage section, Doctor?

15 A. Yes.

16 Q. And can you read that, the first phrase of that?

17 A. "Therapy should begin with three breaths of Tyvaso."

18 It says "should." It doesn't say it has to
19 begin. So it does allow physicians leeway. So it really
20 doesn't change my interpretation on the 2017 protocol.

21 Q. And that was the approved dose of Tyvaso at the time
22 of the 2017 protocol; correct?

23 A. Correct.

24 Q. Okay. Can we -- I want to talk a little bit more
25 about your opinions that you offered regarding whether a

1 POSA would rely on Faria-Urbina. Okay?

2 And I think you said a POSA wouldn't rely on
3 Faria-Urbina; correct?

4 A. Correct.

5 Q. And actually, it's your opinion that the analysis and
6 data in Faria-Urbina is garbage; right?

7 A. I did use that word in my deposition; correct.

8 Q. Okay. And in your opinion, no rational POSA would
9 rely on Faria-Urbina 2018; correct?

10 A. I'm not sure if I used the words "rational POSA," but
11 I don't think a POSA would rely on Faria-Urbina.

12 Q. You testified yesterday, though, that Faria-Urbina
13 was a reference that was relied on in the INCREASE study;
14 right?

15 A. I wouldn't say relied on. It offered a glimmer of
16 hope for patients, but it wasn't relied on.

17 Q. It was cited to in your *New England Journal of*
18 *Medicine* publication along with Agarwal; correct?

19 A. It was, yes.

20 MR. DAVIES: Can we please bring up DTX 10.

21 BY MR. DAVIES:

22 Q. And this should be Saggar 2014, and this was the
23 Saggar 2014 that you also discussed with counsel yesterday;
24 correct?

25 A. Correct.

1 Q. Let's go to page 2. And in Saggar -- you can see
2 Saggar also used CT scans for diagnosing these patients with
3 PH-ILD; correct?

4 A. Correct.

5 Q. You were the associate editor of the *Thorax* journal
6 at the time this paper was published; correct?

7 A. That's correct.

8 Q. And, in fact, you actually, I think you said,
9 facilitated its publication; correct?

10 A. That's correct.

11 Q. And *Thorax* is a highly reviewed, highly regarded,
12 peer-reviewed journal; correct?

13 A. Correct.

14 Q. So in your opinion, Saggar is not garbage; correct?

15 A. It's not garbage.

16 Q. It's your opinion that a POSA would not rely in any
17 way on Saggar 2014 in the context of treating PH-ILD with
18 inhaled treprostinil; correct?

19 A. Not at all. Different mode of delivery, different
20 dose, entirely possible that a different result could
21 emanate. And it was a highly select population with severe
22 pulmonary hypertension. It didn't represent the spectrum of
23 PH-ILD.

24 Q. If you have two drugs, in your opinion, that have a
25 different route of administration and different amount of

1 the drug that's delivered that you described, you wouldn't
2 know how the drug performed; correct?

3 A. Correct.

4 Q. I want to talk a little bit about your opinions
5 related to a reasonable expectation of success.

6 And let's bring up Claim 1 of the '327 patent.

7 And, Doctor, in your opinion, only a randomized,
8 controlled clinical trial would provide a sufficient proof
9 for a POSA to have a reasonable expectation of success with
10 respect to Claim 1 and the other asserted claims of the '327
11 patent; correct?

12 A. A randomized, controlled study as was done would
13 prove the notion of improving exercise capacity.

14 Q. That wasn't quite my question, Doctor. I asked you,
15 in your opinion and the opinions you offered in this case
16 with respect to obviousness and reasonable expectation of
17 success, only a randomized, controlled clinical trial would
18 provide sufficient proof for a POSA to have a reasonable
19 expectation of success with respect to the claims of the
20 '327 patent; correct?

21 A. Yes.

22 Q. And anything less than a randomized, controlled
23 clinical trial could not establish a reasonable expectation
24 of success, in your opinion; right?

25 A. If we're talking generally versus with regard to

1 specifically to inhaled treprostinil, it would probably be a
2 different answer. If you have, you know, multiple
3 retrospective analyses --

4 Q. Doctor, my question was more specific than that. I'm
5 just asking with respect to your obviousness opinions in
6 this claim and specifically with respect to a reasonable
7 expectation of success that you've offered opinions on in
8 this case for the claims, in your opinion, anything less
9 than a randomized, controlled clinical trial could not have
10 provided a POSA with a reasonable expectation of success
11 with respect to the claims of the '327 patent; correct?

12 A. In this case, the answer is correct.

13 Q. And, in fact, in your opinion, nothing short of the
14 actual INCREASE trial results could provide a POSA with a
15 reasonable expectation of success with respect to the
16 claims; right?

17 A. Correct.

18 Q. That was the understanding you applied for your
19 analysis in this case; right?

20 A. Correct.

21 Q. I'd like now to discuss a little bit your opinions on
22 inherency. I'm sorry. Can we bring Claim 1 back up.

23 It's your opinion that Claim 1 requires
24 virtually all of these PH-ILD patients experience an
25 improvement in exercise capacity; correct?

1 A. No. I never said "virtually all."

2 Q. Okay. What is the standard that you're applying for
3 inherency?

4 A. Well, for inherency, just that I understand
5 correctly, it's the prior art inferring that the claim is
6 true. Yes, you do need patients to unequivocally have this
7 response in terms of exercise capacity. Inevitably and
8 invariably, they should have this response.

9 MR. DAVIES: Can we bring up PDX 7.3.

10 BY MR. DAVIES:

11 Q. And you talked yesterday about the fact that the
12 asserted claims are not inherently anticipated; correct?

13 A. I did.

14 Q. And it's your opinion today you did not require that
15 virtually all the PH-ILD patients experience improvement in
16 exercise capacity to render Claim 1 inherent; correct?

17 A. Could you repeat that, please.

18 Q. I don't know if I can.

19 THE COURT: Ask another question.

20 BY MR. DAVIES:

21 Q. With respect to Claim 1, is it your opinion that
22 Claim 1 requires all -- virtually all PH-ILD patients to
23 experience improvement in exercise capacity to be inherently
24 anticipated?

25 A. Yes.

1 Q. Okay. And you applied that same requirement for
2 inherent anticipation for all the other asserted claims in
3 this case; right?

4 A. Correct.

5 Q. Dr. Nathan, yesterday Dr. Wertheim provided some
6 opinions related to percent predicted FVC and absolute FVC.
7 Were you here for those?

8 A. I was.

9 Q. And in your opinion, absolute FVC is more valid
10 because you're measuring the patients against themselves at
11 baseline and not the percent predicted; correct?

12 A. I think the two are complementary and it depends in
13 what context you're looking at each of these.

14 MR. DAVIES: Can we bring up page 59 of
15 Dr. Nathan's -- it would be the 2025 deposition. It's going
16 to be starting at -- let's just bring up 59.

17 BY MR. DAVIES:

18 Q. So I was asking you some questions here about the use
19 of FVC measurements in the TETON trial; correct?

20 A. Yes.

21 Q. And the TETON trial is a trial that UTC is conducting
22 to attempt to verify the results of the FVC data that they
23 saw in the INCREASE trial; correct?

24 A. Correct.

25 Q. Because, in your opinion, the FVC data from the

1 INCREASE trial, without further validation, is just
2 hypothesis-generating; correct?

3 A. It's hypothesis-generating with regards to broader
4 group and that's what we're looking at in the TETON study.
5 We're not looking at PH-ILD. We're looking at patients with
6 IPF and it's agnostic as to whether or not they have
7 pulmonary hypertension or not.

8 Q. And if we look at your deposition transcript from
9 earlier in this case, you can see you were asked: "Why did
10 you choose absolute FVC as the measure of primary efficacy
11 in the TETON trial as opposed to percent predicted FVC?"

12 And in your answer, you identified absolute FVC
13 is for the standard for many of the IPF clinical trials.

14 And then you were asked: "Do you know why
15 that's been the standard, absolute versus percent
16 predicted?"

17 And you said a couple of things about percent
18 predicted and then you respond: "Absolute is more valid, in
19 my viewpoint, because you're measuring the patient against
20 themselves at baseline and not the percent predicted."

21 Is that the answer you gave?

22 A. I did.

23 MR. DAVIES: I have no further questions at this
24 time, Your Honor.

25 THE COURT: Thank you.

1 Redirect, Mr. Jackson.

2 MR. JACKSON: Just a few quick things.

3 REDIRECT EXAMINATION

4 BY MR. JACKSON:

5 Q. Now, just now on cross, Mr. Davies put before you DTX
6 62, was it?

7 MR. JACKSON: Mr. Smith, can you put that up,
8 please.

9 BY MR. JACKSON:

10 Q. And this is the '507 patent that he put in front of
11 you; correct?

12 A. Correct.

13 Q. Have you ever seen this patent before today?

14 A. I have not.

15 Q. Did Mr. Davies, after he put it up and moved it into
16 evidence, ask you any questions about this patent?

17 A. He didn't ask specific questions about the patent.

18 Q. He just moved it into evidence and moved on; correct?

19 A. Correct.

20 Q. A minute ago, you were just asked about the
21 reasonable expectation of success. And Mr. Davies asked you
22 something about a reasonable expectation -- only a
23 randomized, clinical trial would give a reasonable
24 expectation of success and anything else would not establish
25 that reasonable expectation.

1 Do you recall that exchange?

2 A. I do.

3 Q. Why do you have that view?

4 A. Because in this situation, there was such
5 overwhelming evidence that using PH therapies for PH-ILD did
6 not work. There was a lot of evidence of harm in patients
7 who had previously been treated in randomized, controlled
8 studied with PAH medication that, in this case, you needed a
9 very well-done, large, randomized, controlled study to show
10 and prove efficacy. It had a mountain of evidence it had to
11 overcome in order to prove that Tyvaso works for PH-ILD.

12 Q. Is that based on those six studies we keep looking at
13 in this case?

14 A. That's correct.

15 Q. And Mr. Davies asked you a lot of questions about the
16 '327 patent and dry powder.

17 Do you recall these questions?

18 A. I do.

19 MR. JACKSON: Can you go -- Mr. Smith, can you
20 pull up the '327 patent.

21 BY MR. JACKSON:

22 Q. You were asked about the need to get -- or about
23 aspects of the dry powder.

24 Do you remember that?

25 A. I do.

1 Q. And when you were asked -- actually, strike that.

2 When United Therapeutics was -- sought FDA
3 approval to get approval of its dry powder product, did the
4 FDA require United Therapeutics to submit any dry powder
5 information?

6 A. Yes, they did.

7 Q. What did they require United Therapeutics to submit?

8 A. There were PK studies, pharmacokinetic studies,
9 showing equivalence or that it resulted in the same blood
10 levels.

11 And then there was a conversion study. I get
12 confused between the acronyms. I think it was the BREEZE
13 study that showed patients could be converted from the
14 nebulized form to the DPI version safely and effectively.

15 Q. So that's additional information the FDA required so
16 that United Therapeutics could move from the nebulized
17 version to the dry powder version; is that right?

18 A. That's correct.

19 Q. Was any of that information available to a POA as of
20 April 2020?

21 A. No. The approval for the DPI came after that. And
22 so I believe the data supporting that was after April 2020.

23 Q. And so the safety and PK data for the dry powder all
24 came after April 2020; is that correct?

25 A. I believe so.

1 Q. And did any of the data exist otherwise in the
2 literature prior to April 2020?

3 A. No, not to my knowledge.

4 MR. JACKSON: Can you actually go to Tables 4
5 and 5. I think it's on page 40 -- Example 4 and 5 on
6 pages 46 and 47.

7 BY MR. JACKSON:

8 Q. Are Examples 4 and 5 those studies?

9 A. It's a little blurry.

10 Q. Do you see Example 4 on page 46?

11 A. Yes.

12 Q. Is that the study you were just referencing?

13 A. Yes.

14 Q. And if you look at Example 5, is that also another
15 study you were just referencing that was not available as of
16 April 2020?

17 A. Yes.

18 Q. To a POSA, that is?

19 A. Correct.

20 MR. JACKSON: Nothing further. Your Honor.

21 THE COURT: All right. Thank you, Dr. Nathan.
22 I think you're finally done, so you can step down. Watch
23 your step.

24 THE WITNESS: Thank you, Your Honor.

25 MR. JACKSON: And with that, Your Honor, we rest

1 our responsive case to their validity case.

2 THE COURT: Okay. Thank you.

3 MR. SUKDUANG: And, Your Honor, given the time,
4 we're not going to call Dr. Ogenstad. So I believe we have
5 now closed our rebuttal to their rebuttal.

6 THE COURT: Okay. All right. So we're finished
7 with the evidence portion of this case.

8 You know, in terms of the exhibits, I think you
9 all are going to owe the deputy clerk some kind of
10 identification of the exhibits that appear twice. But that
11 doesn't have to be done now.

12 Is there anything we should do before
13 reconvening at 11:30 for your arguments?

14 MR. SUKDUANG: Nothing from Liquidia.

15 MR. JACKSON: I think that addresses it for
16 United Therapeutics. Thank you, Your Honor.

17 MR. SUKDUANG: It will be 11:30, Your Honor?

18 THE COURT: 11:30. And when arguments are over,
19 I hope you will be ready to discuss the post-trial
20 submissions timing, like -- things like that.

21 MR. JACKSON: Yes, Your Honor. And to the
22 degree it matters, we would actually like our 52(c) motion
23 resolved on the regular -- not on the basis of the -- all of
24 the post-trial briefing can be resolved quicker.

25 And the reason we ask that is because we are

1 right here and there is a bar for them being on the market
2 for this. It's a statutory bar, and they are currently on
3 the market. So we would like that -- obviously, to have
4 that addressed sooner rather than later.

5 MR. SUKDUANG: And, Your Honor, I think you
6 addressed this yesterday. I had asked you that same
7 question yesterday and you said do it in the post-trial
8 briefs.

9 THE COURT: All right. Well, it's not going to
10 be done today. So you can bring that up again after we've
11 had the arguments. Okay. So --

12 MR. SUKDUANG: And in terms of the briefing
13 schedule, I believe we sent a proposal to UTC.

14 THE COURT: Okay. No need to tell me about it.
15 Just try to get to someplace where -- see what you can come
16 up with between yourselves. Okay?

17 MR. SUKDUANG: Okay.

18 THE COURT: We'll be in recess until 11:30.

19 (A recess was taken, after which the following
20 proceedings were had:)

21 THE COURT: All right. Please be seated.

22 It occurs to me that one thing that I should
23 have done when I was talking to you before was suggest that
24 the way we do this is plaintiff goes first and speaks about
25 infringement. So probably not for very long but -- or

1 however long they want, and then they reserve the rest of it
2 to respond to the defendant going first on invalidity.

3 MR. SUKDUANG: So I respond to him on
4 infringement and then do the rest, and then he responds to
5 me?

6 THE COURT: Yeah, yeah, you do it all as a
7 package, but his invalidity -- or the plaintiff's invalidity
8 response is after you've made your arguments on invalidity.

9 MR. SUKDUANG: That's fine with me, Your Honor.

10 THE COURT: Okay. All right. So, Mr. Carsten,
11 I guess.

12 MR. CARSTEN: Yes, Your Honor. I have a few
13 slides. May I approach, Judge?

14 THE COURT: Sure.

15 MR. CARSTEN: Thank you. And I promise not to
16 read slides at you. I've taken your admonition to heart.

17 THE COURT: Okay.

18 MR. CARSTEN: So just to jump right in on that
19 PDX 8.3, Your Honor, Liquidia elected to choose that
20 505(b)(2) pathway in which it relied exclusively on UTC
21 Tyvaso's clinical efficacy data for approval.

22 And to be clear, the label itself -- now mind
23 you, we're only talking about Claims 5, 6, 9, and 17. 1 and
24 14 are stipulated.

25 THE COURT: Yes.

1 MR. CARSTEN: The label itself includes data
2 pertaining to the six-minute walk distance. So the label
3 itself, in our view, establishes infringement for that
4 claim.

5 And furthermore, because the label itself cites
6 to INCREASE and the method used or described in that label
7 would give rise to, more likely than not, the benefits of
8 the therapeutic effects specified in Claims 5, 6, and 9, we
9 believe those are met as well.

10 I'm reminded of the -- it's sort of déjà vu all
11 over again. Three years ago we were here in front of the
12 '793 patent -- in front of you for the '793 patent. And you
13 had held that the '793 patent was pertaining to hemodynamic
14 effects.

15 And the same argument was made: There's no
16 hemodynamic effects specified in the label. There's no
17 requirement to measure. And Your Honor said, you know, it
18 just needs to instruct doctors and patients to administer a
19 single-event dose that is therapeutically effective. The
20 LIQ 861 label does so by instructing doctors and patients to
21 administer it.

22 That's exactly what we have here.

23 But even if there were not enough, we have a
24 launch, and so we're able to look outside the label,
25 assuming you're limited to--

1 THE COURT: But we don't have any evidence about
2 the launch on the record; right?

3 MR. CARSTEN: Well, I did ask Dr. Channick about
4 that and he confirmed that the product was on the market.

5 But regardless, the label -- the FDA -- Liquidia
6 petitioned the FDA for the supplemental NDA on this matter
7 and said, we want to rely upon not just the package insert
8 for Tyvaso, but also treprostinil peer-reviewed literature.
9 And the FDA agreed and allowed it over that.

10 And so when you include the Yutrepia label with
11 the INCREASE publication, there is no doubt that, more
12 likely than not, a patient receiving this -- the drug under
13 the claimed method would experience those therapeutic
14 effects of 5, 6, and 9.

15 THE COURT: So in 6 and 9 where the therapeutic
16 effect was described as a statistically significant
17 reduction, what does -- how is that measured? Or how is
18 that determined? Whether or not something that's going to
19 occur in the future and following the method that's
20 described in Claim 1, how are we going to know what number
21 is a statistically significant reduction?

22 MR. CARSTEN: Well, Your Honor, I think that's
23 exactly the crux of medicine here; right? So you have the
24 clinical trial which establishes efficacy for -- in this
25 population by a statistically significant measure.

1 Once you have that, then you know that it's more
2 likely than not that a patient being administered this
3 method and receiving the drug, if they see a benefit, it
4 will be a statistically significant one.

5 Now, there's additional claims --

6 THE COURT: So wait. So statistically
7 significant is -- because you can't tell whether something
8 is statistically significant when it happens to one person.

9 Is this -- is the claim, essentially,
10 incorporating by the reference to a statistically
11 significant reduction the numbers that are described as
12 statistically significant in the INCREASE trial publication?

13 MR. CARSTEN: No, Your Honor. We don't see it
14 that way. And I think Dr. Thisted did try to explain this,
15 that it's not as if there's a statistical significance
16 hurdle that -- for example, and I think we saw 1.07 percent
17 for FVC percent predicted increase and a p-value that said
18 that's statistically significant.

19 THE COURT: Right.

20 MR. CARSTEN: But that was the average over the
21 entire -- or the statistical measure over the whole
22 population.

23 So it's not as if, if a patient sees a 1.07
24 percent benefit, if they're over that, it's statistically
25 significant, and if they're under that, it's not.

1 What these claims require --

2 THE COURT: So if that's not the measure, what
3 is the measure in a particular patient? If they do .59,
4 does that meet the claim?

5 MR. CARSTEN: Yes, Your Honor, we believe it
6 would.

7 THE COURT: If they do minus .16, does that meet
8 the claim?

9 MR. CARSTEN: Well, minus .16, I think there's a
10 situation where the patient would not be receiving the
11 therapeutic effect benefit. And so that --

12 THE COURT: Any increase at all no matter how
13 small, that meets the claim?

14 MR. CARSTEN: I believe that is correct, Your
15 Honor. Because that patient would be a member of the
16 population as if -- and so we know that on a population
17 basis, that that patient would be included in the
18 therapeutic benefit category, and that number populated that
19 statistically significant determination.

20 And so Your Honor could think about this as a
21 hurdle, but remember, these claims don't require a
22 measurement. They don't require that there's any actual
23 measurement. Just like the hemodynamic benefit in the '793
24 wasn't required to be an actual measurement.

25 THE COURT: But it's hard to say it doesn't

1 require a measurement when it's talking about improvements
2 in things that can be measured.

3 MR. CARSTEN: I understand, Your Honor. But I
4 think we had this discussion with Dr. Channick when he was
5 on the stand. And that is, do you disagree, sir, that a
6 patient receiving this treatment under this method would
7 more likely than not experience that benefit. And even if
8 it's not measured.

9 We're talking about in the context --

10 THE COURT: You're saying -- when you say more
11 likely than not experience this benefit, the benefit in your
12 position is the benefit is any non-zero benefit in anything
13 that was measured in the INCREASE trial?

14 MR. CARSTEN: Yeah, if -- well, not exactly. I
15 think for Claim 5, for example, you have to be looking at --

16 THE COURT: Well, Claim 5 -- I'm not talking
17 about Claim 5. That gives an actual measurement. And yes,
18 it seems to me, there's a very reasonable basis to believe
19 that people who are treated with this, a substantial number
20 of them will meet that.

21 MR. CARSTEN: Right.

22 THE COURT: But I'm asking about Claim 6 and 9.

23 MR. CARSTEN: Oh, I see.

24 With respect to exacerbations, in the
25 statistical population, it's tough to say there is a

1 reduction of exacerbations. As Your Honor will remember,
2 that's a serious event that usually, typically leads to
3 somebody going to the hospital; right?

4 And it's tough to say, well, because you took
5 this drug, you didn't have one of those events. But on the
6 population basis, that was one of the surprising results
7 from INCREASE, was that we're able to determine that people
8 who take the drug are, more likely than not, going to
9 experience that benefit.

10 THE COURT: So even an individual who suffers a
11 bunch of exacerbations, logically, there's no reason why
12 they aren't included in the claim even though they're
13 getting less-than-zero benefit probably?

14 MR. CARSTEN: The statistical analysis shows
15 that if that patient were -- had been in the INCREASE
16 protocol and the INCREASE trial, it was more likely than not
17 that they would have seen that benefit.

18 And so that's the proof that establishes and
19 allows confidence for the treating physician to say, I'm
20 going to give you this drug product according to the label,
21 and I expect that it's going to provide you with reduced
22 excursions -- or exacerbations, excuse me.

23 THE COURT: Well, the claims are that it
24 provided, not that it's expected. The claims are they will
25 happen.

1 MR. CARSTEN: Right. And it's -- and the
2 infringement standard is more likely than not.

3 And I submit that the label in combination with
4 the INCREASE data establishes it's more likely than not for
5 a patient having received the drug product that they will
6 receive -- they will experience a reduced number of
7 exacerbations.

8 THE COURT: So earlier when I asked you -- we
9 were talking about not exacerbations but maybe something
10 more like the forced vital capacity. Even though the claim
11 talks about providing a statistically significant
12 improvement, a patient who gets a non-zero improvement is
13 someone who is having the method practiced on them, in your
14 opinion?

15 MR. CARSTEN: Yes, Your Honor.

16 THE COURT: Okay. I'm sorry. I don't want to
17 use up all your time with my questions.

18 MR. CARSTEN: Thank you, Your Honor. If you
19 have -- we're here at your pleasure. So if Your Honor has
20 questions, I'd rather spend the time addressing that.

21 THE COURT: That's the main question I have
22 about infringement at this time.

23 MR. CARSTEN: Thank you, Your Honor.

24 THE COURT: All right. Mr. Sukduang.

25 MR. SUKDUANG: Just so I can try to keep track

1 of time, Your Honor.

2 THE COURT: As long as you're not recording us.

3 MR. SUKDUANG: I'm not recording. I don't want
4 to hear myself. I'm thankful that you're willing to listen
5 to me. I have documents, slides I'd like to hand up. May I
6 approach, Your Honor?

7 THE COURT: Yes.

8 MR. SUKDUANG: May I begin, Your Honor?

9 THE COURT: Yes.

10 MR. SUKDUANG: Sanya Sukduang for Liquidia.

11 Your Honor, as I started in my opening, UTC was
12 able to get a label expansion for PH-ILD which is now on the
13 Tyvaso label in 2021. They did that using the exact same
14 drug, Tyvaso; the exact same route of administration,
15 inhalation; the exact same formulation, solution; and using
16 the exact same dosing. In fact, the 2009 dosing is the same
17 as '21 dosing.

18 How did they do that? They did it through the
19 INCREASE study, as you heard. And not only did they get a
20 label expansion, they have a patent expansion, the '327
21 patent, and that '327 patent goes 20 more years longer than
22 any other patent they have listed in the *Orange Book* for
23 Tyvaso or Tyvaso DPI.

24 How did they get there?

25 THE COURT: Let me interrupt you for a second.

1 You could be -- you, Liquidia, also decided to get a label
2 expansion, so to speak. You could be on the market with no
3 questions if you had just gone with the initial indication;
4 right?

5 MR. SUKDUANG: With respect to this particular
6 patent, the '327 patent?

7 THE COURT: Yeah.

8 MR. SUKDUANG: Yes. But then we had the '793,
9 which we litigated.

10 THE COURT: But that's gone.

11 MR. SUKDUANG: And there's a new lawsuit --
12 without the '327 patent, yes. That pertains to PH-ILD only.

13 THE COURT: So to some extent, while you're
14 talking about them getting a label expansion, your being
15 blocked on the market for another 20 years is at least
16 partly because of your decision to try to get the whole
17 market and not just the part of the market that to date you
18 have won.

19 MR. SUKDUANG: It's not based on us trying the
20 get the whole market. It's based on them getting another
21 patent and never this product. And how did they do that?
22 That's the point, Your Honor.

23 What UTC is trying to do is stop doctors from
24 doing exactly what they were doing since 2009, unless they
25 buy their drug. And UTC, the record is clear since 2009,

1 doctors like Dr. Sagggar, Waxman, Tapson, Channick, and Hill
2 use Tyvaso to treat PH-ILD patients. And I know you're
3 going to have to assess whether the record says that, but
4 that's what the testimony was. That's what the documents
5 show. They used Tyvaso to treat PH-ILD patients. They
6 used --

7 THE COURT: For what it's worth, I don't
8 actually have a lot of hesitation in saying that I credit
9 their testimony that that's what they were doing.

10 MR. SUKDUANG: Your Honor, I appreciate that.
11 How it all happened is they did this: They reported those
12 outcomes to UTC. Dr. Waxman, Tapson, and Dr. Sagggar wrote
13 those outcomes down for Faria-Urbina and Parikh in
14 peer-reviewed journals, and Sagggar, peer-reviewed journals.
15 They told everybody they did this.

16 And Dr. Waxman went to UTC and you heard this
17 from UTC witnesses themselves. Dr. Smith, Mr. Laliberte,
18 the conception or the idea of INCREASE itself was based from
19 Dr. Waxman's presentation in 2015 and the Agarwal data.
20 That's how they started INCREASE and that's where INCREASE
21 went from there. And Dr. Waxman gave them the dosing and
22 the patient population.

23 And what they want to do -- they're fine. They
24 did the INCREASE study. That's not the problem. The
25 problem is they're taking someone else's work in the prior

1 art and now trying to get a claim on that and stop everybody
2 from doing what they were already doing unless they buy
3 Tyvaso. And we get to the infringement, Your Honor.

4 And if we could bring up the claims, please.

5 I'm going to focus on 5, 6, 9, and 17. You
6 heard from Liquidia's Mr. Adair, who testified by video,
7 that Liquidia cannot promote, instruct, encourage a doctor
8 to do anything that's not approved on the FDA label.
9 Dr. Nathan, Dr. Channick, Dr. Hill agreed with that.
10 Liquidia can't do that. UTC can't do that.

11 THE COURT: But you can actually do that as of
12 today; right?

13 MR. SUKDUANG: I can tell you for a fact when
14 you look at the Yutrepia label, we are not doing that. We
15 are not encouraging, instructing, anything with respect to
16 NT-proBNP FVC --

17 THE COURT: But you are instructing how to,
18 let's say, perform the method. Leave aside the results.

19 MR. SUKDUANG: Of Claim 1. We admitted
20 infringement of Claim 1. So we are -- on our label, we give
21 a dose, and we say "exercise capacity." So you're right and
22 we acknowledge that. So there's no dispute with that with
23 respect to Claim 1.

24 The issue is the other claims. We still have to
25 instruct, encourage, induce those other things. And

1 Dr. Nathan agreed with Mr. Adair that Liquidia cannot do
2 that. Dr. Nathan agreed that the Yutrepia label is not
3 indicated for NT-proBNP in any manner, for FVC in any
4 manner, for exacerbations of ILD in any manner. It's not
5 approved for six-minute walk distance or 10 meters. That is
6 not the indication.

7 And you do not have to run a six-minute walk
8 distance to assess exercise capacity. Dr. Nathan agreed.
9 Dr. Channick agreed. Dr. Hill agreed. Dr. Waxman provided
10 testimony that he prefers the three-minute walk test, step
11 test. And that you can also -- the most convincing evidence
12 is a patient coming in and saying, "Hey, I can walk to my
13 mailbox and before I couldn't get off the couch."

14 All of those are valid measurements of exercise
15 capacity that doctors use in real-world clinical practice.
16 Six-minute walk test might be done in clinical trial. We're
17 not talking about the clinical trial here.

18 Dr. Nathan agreed NT-proBNP, FVC, exacerbations,
19 those words are nowhere on the Yutrepia label and no data
20 related to those are on the Yutrepia label. There's no
21 instruction to treat more than one patient at a time.
22 There's no instruction to conduct any statistical analysis,
23 to aggregate data, nothing with that. There is nothing on
24 the label, in our opinion, that would lead to direct
25 infringement of the dependent claims.

1 You were going to ask a question, it looks like.

2 THE COURT: I thought you were going to say
3 there to indirect infringement.

4 MR. SUKDUANG: I'm getting to direct first
5 because doctors have to directly infringe. Doing Claim 1,
6 every single one of these claims -- 5, 6, 9, 17, and
7 Claim 1 -- require some type of measurement or outcome to be
8 observed. They require it. The NT-proBNP has to happen.

9 THE COURT: It has to happen. They don't
10 certainly have to measure.

11 MR. SUKDUANG: Then how do you know?

12 THE COURT: That's a different question. But it
13 doesn't say you have to measure it.

14 MR. SUKDUANG: As you pointed out, 200 picograms
15 is the specific value the claim requires. Dr. Channick
16 testified that you cannot know 200 picograms was met unless
17 you measure NT-proBNP before you administer and then measure
18 at some point after 8, 12, 16 weeks. It just doesn't
19 happen. And how do we know that? Because the INCREASE
20 trial didn't have it happen all the time. So these claims
21 require something to be done.

22 THE COURT: I don't think I'm going to agree
23 with you on that.

24 MR. SUKDUANG: I'll move on to the next issue
25 with respect the inducement. Again, with respect to

1 inducement, there has to be something on the label doing
2 this. When you looked at Dr. Nathan's for Claims 5, 6, and
3 9, the only thing pointed to was *New England Journal of*
4 *Medicine* article. That's the only thing he pointed to.

5 THE COURT: The one that reports the results of
6 the study?

7 MR. SUKDUANG: Yes. The Waxman paper.
8 Dr. Nathan testified that the only thing a doctor needs to
9 read to safely and effectively treat patients with Yutrepia
10 is the label itself. He testified that the *New England*
11 *Journal of Medicine* article is not cited in the Yutrepia
12 label. It's not incorporated by reference. It's not
13 directed. There's nothing in the Yutrepia label that tells
14 doctors to go read something outside the label with respect
15 to any of those claims.

16 Dr. Hill, Dr. Channick --

17 THE COURT: So Mr. Carsten said -- and I have no
18 independent memory at this time -- that you made a similar
19 argument regarding hemodynamics in the '793 patent and that
20 I, nevertheless, ruled against you. Assuming that's true,
21 why is this any different?

22 MR. SUKDUANG: Because those claims are entirely
23 different. Those claims don't have these outcomes required.
24 Those claims, the '793 claims, say give the drug by inhaled
25 in a therapeutic amount in a single-administration dose.

1 That's it. There was nothing in those claims that said, oh,
2 this number has to be reached, a statistical significance
3 needs to be reached.

4 THE COURT: You're saying in so many words what
5 I decided three years ago about hemodynamics was, I guess,
6 the therapeutic effect that the hemodynamics showed there
7 was indicated?

8 MR. SUKDUANG: The hemodynamic effect showed
9 just pulmonary hypertension. And remember, pulmonary
10 hypertension is just, as we heard, those hemodynamics;
11 right? These are completely different claims in terms of
12 the outcome --

13 THE COURT: Okay. Well, so let's not argue.

14 MR. SUKDUANG: So on inducement --

15 THE COURT: So, you know, that's something that
16 you can bring up in your briefing.

17 MR. SUKDUANG: Sure.

18 THE COURT: Or he can bring it up in the
19 briefing and I'll sort that out later.

20 So go ahead.

21 MR. SUKDUANG: So on inducement, again, the
22 label has to instruct. There's no instruction to do
23 anything in 5, 6, 9, or 17. It's not indicated for. It's
24 not in the label. Dr. Nathan agreed. Dr. Channick
25 testified to that. Liquidia cannot do anything that is not

1 in the label.

2 What Dr. Nathan pointed to was the *New England*
3 *Journal of Medicine*. I spoke about that. It's not in
4 there. The second thing, the only other thing he pointed
5 to, was a product dossier for Yutrepia. And he admitted and
6 Dr. Channick agreed that the product dossier is not meant
7 for doctors. It's meant for insurance companies.

8 So they're not instructions for doctors on how
9 to use Yutrepia. And in the product dossier itself on page
10 2, Dr. Nathan and Dr. Channick agree that it says this is
11 not marketing material and it is not instructions on how to
12 use Yutrepia. You have to go to the label for that.

13 With respect to the Yutrepia label, Dr. Nathan
14 didn't point to this, but Section 6.1 says: "With respect
15 to Yutrepia, you cannot take clinical trials with a
16 different drug and equate them to Yutrepia."

17 That is the instruction on the Yutrepia label
18 itself. The FDA had to review that. If they disagreed with
19 that, they would have made us remove it. When you look at
20 the totality of the Yutrepia label, we believe there's no
21 direct infringement.

22 But more importantly, to inducement of
23 infringement, Your Honor, there is nothing inducing
24 infringement of Claims 5, 6, 9, and 17. The simple fact
25 that --

1 THE COURT: I understand your argument. And
2 basically, what you're saying and will presumably cover in
3 the briefing is, essentially, the legal point that what you
4 seem to be saying is unless there's an express instruction
5 that has all the elements of the claim, you can't be
6 inducing infringement.

7 MR. SUKDUANG: I think whether you look at
8 expressed or implicit, there's neither here. It's an
9 absence. And in that instance, Your Honor --

10 THE COURT: So you could add something where it
11 doesn't expressly indicate an element of the claim, but it
12 could be implicit, and then that would be inducing?

13 MR. SUKDUANG: No. You can't have an implicit
14 inducement.

15 THE COURT: Why did you just a moment ago say it
16 doesn't have anything --

17 MR. SUKDUANG: No, I said the label doesn't. I
18 apologize if I misconstrued your question.

19 THE COURT: Well, let's put it another way, just
20 you were saying -- you said it doesn't have an express or
21 implicit, you know, direction to do this, so I took it you
22 were saying that the reason to say that is if an implicit
23 was -- counted for inducement --

24 MR. SUKDUANG: Okay. I understand.

25 THE COURT: Do you understand what I'm saying?

1 MR. SUKDUANG: I do.

2 No. Implicit cannot count for inducement.

3 There has to be specific intent, specific intent on
4 Liquidia's part to provide instructions to induce
5 infringement of that claim.

6 Implicit -- and this goes to the skinny label
7 world. We're not a generic drug, but a generic drug --
8 every doctor knows for a generic drug, if there's two
9 indications -- and a generic skinny label is about one --
10 every doctor already knows that that generic drug, because
11 of Hatch-Waxman pathway, can be used for that other
12 indication. That it would work; right?

13 But they can skinny-label it out. And that
14 creates no inducement. Under your scenario, that would also
15 be implicit because everybody just knows and you just say
16 drug X and here's the dose.

17 In those situations, the Federal Circuit has
18 held that is not induced infringement. You have to have
19 explicit instructions to do so. Otherwise, the skinny-label
20 world would -- could not exist. It would not exist.

21 And under UTC's scenario, that is exactly what
22 they're arguing. They're saying, you don't have to have it
23 on the label. Just look at the results of the clinical
24 trial. If that's the case, then every generic drug that
25 tries to skinny label would infringe a claim directed to an

1 indication that is not on the label.

2 It would infringe any claim directed to the
3 outcome of that method on that patent even though it's not
4 on the label. And we know that is not the law.

5 Moving to obviousness, Your Honor, if I may. Is
6 that okay?

7 THE COURT: Yes.

8 MR. SUKDUANG: Moving to obviousness,
9 Faria-Urbina, the '793 patent, and Saggar 2014 render all
10 the claims obvious.

11 THE COURT: Okay. And so I don't want to dig a
12 deeper -- a deep core here, but in terms of the status of
13 the '793 patent as prior art, can you just give me the
14 one-sentence preview of what your response to the motion --

15 MR. SUKDUANG: It might be one long sentence.

16 One, it's prior art under 102(a)(1).

17 Two, it's admitted prior art in the '793 patent.
18 Under the law, they can't get that.

19 Three --

20 THE COURT: Wait. So I understand it's prior
21 art under 102(a)(1). I understand that, those words. And
22 is that -- why is that?

23 MR. SUKDUANG: Because the disclosure was
24 available to the public before the effective filing date of
25 the '327 patent. The disclosure that's in the '793 patent

1 was available to the public prior to the effective filing
2 date of the '327 patent.

3 THE COURT: And you say the disclosure because
4 it was in the priority chain or because --

5 MR. SUKDUANG: It's -- well, we believe, one,
6 it's in the patent itself, but it's also in the priority
7 chain.

8 THE COURT: But the patent itself, did that
9 become public before it was issued?

10 MR. SUKDUANG: Did the -- the application was
11 published -- yeah, it was published before it was issued.
12 That's the way, the normal course of --

13 THE COURT: Well, it depends on how fast. I
14 thought it was 18 months.

15 MR. SUKDUANG: It didn't go that fast. And with
16 respect to the disclosure, it's out there. It's admitted
17 prior art in the '327 patent.

18 THE COURT: What do you mean, it's admitted
19 prior art?

20 MR. SUKDUANG: So under the law, if someone
21 admits that the disclosure or the information is in the
22 prior art, then it's a -- then they can't escape that
23 admission.

24 THE COURT: And there's somewhere in the '327
25 patent, where these inventors say the '793 patent is prior

1 art?

2 MR. SUKDUANG: They say it's disclosed. And
3 what the case law says, that you don't have to say it's
4 prior art. You just say the subject matter is disclosed.
5 That's what they did with the '793 itself.

6 With the '507, which is the same spec, with that
7 W0/2019, they pointed to all that. In fact, UTC -- and the
8 reason why priority -- I looked back at the transcript, Your
9 Honor. With respect to priority not being contested, that
10 was with respect to our 2020 invalidity, the February 2020
11 press release defense that we withdrew because you said we
12 didn't bring it up on time.

13 THE COURT: I think we did all that before we
14 had the pretrial conference.

15 MR. SUKDUANG: No, no, no. We withdrew it going
16 into the pretrial conference because you issued a ruling on
17 that. That forced us to do it before the pretrial
18 conference.

19 THE COURT: Right. So that's not what --

20 MR. SUKDUANG: I mean, we would have kept it in
21 had you not said we couldn't, so.

22 THE COURT: Right, right. But in other words,
23 it was gone so -- I don't understand why the fact that you
24 were raising priority with something that was now gone has
25 any impact on what you said at the pretrial conference or

1 what the plaintiff said that you obviously should have
2 objected to if it wasn't true.

3 MR. SUKDUANG: Well, because the way -- when you
4 read the transcript, Your Honor asked is this priority issue
5 moot, because they had a motion on the -- they had a motion
6 which -- it's not a Daubert motion. It was the objections
7 to report and recommendations of the magistrate judge. And
8 that -- with that issue, the priority became moot.

9 And when you read the transcript, what was --
10 what was discussed about that issue, they didn't bring up
11 '793 priority -- prior art. And we believe it is, but now
12 they're saying it's not prior art.

13 And when they're saying it's not prior art, in
14 the pretrial order itself, paragraph 15 says they have to
15 present evidence if there's prior art that they contend is
16 after April 20th. They have to present evidence
17 establishing their --

18 THE COURT: Oh, so that's -- you know, I was
19 wondering in the pretrial order -- so we'll come back to
20 this, but why don't we just assume it's prior art and move
21 on.

22 MR. SUKDUANG: Okay. I apologize, Your Honor.

23 THE COURT: No, no, no, no. I'm the one that
24 brought it up. But I'm not apologizing so you don't need to
25 apologize.

1 MR. SUKDUANG: I wish my life worked like that
2 most of the time, but thank you, Your Honor.

3 So going back to what I was saying,
4 Faria-Urbina, '793 patent, and Saggar render all the claims
5 obvious. There's ample motivation to combine those three
6 references. As Dr. Channick testified, all three are
7 directed to treprostinil. All three are directed to PH-ILD.
8 All three disclose the exact dosing in Claim 1 of the '793
9 patent. And they all disclose improving exercise capacity
10 explicitly.

11 With respect to Faria-Urbina and the '793
12 patent, they're also directed to the same group of
13 administration, inhaled. There's ample motivation to
14 combine those because they teach the same patient population
15 using the same drug and the same dosing to try to achieve
16 the same outcome. That's motivation to combine.

17 A person with skill in the art would be
18 motivated to combine Saggar even though Saggar is IV
19 treprostinil. Why is that? Again, the exact same drug.
20 They're treprostinil. They work in the same mechanism of
21 action. They're looking at the same patient population.

22 And as Dr. Channick testified, a person of
23 skill -- and remember, Saggar is before both of these. A
24 person of skill in the art would look at Saggar and say, oh,
25 these are good findings, but as other people recognized,

1 maybe there's an issue with systemic vasodilators.

2 Saggar didn't see it, but let's just avoid that
3 issue altogether and go to inhaled. So you combine what you
4 get from Saggar and IV, you'd go to the inhaled route
5 because, as everybody testified, when you inhale it, it's
6 localized administration. You avoid that potential systemic
7 side effect. There's ample motivation to combine.

8 Dr. Nathan's testimony about the seven deadly
9 studies further supports the motivation to combine Saggar
10 with Faria-Urbina and '793. There's no dispute that those
11 studies don't involve treprostinil and there's no dispute
12 that six of them deal with oral administration of
13 non-treprostinil drugs.

14 But Dr. Nathan testified yesterday that they all
15 have the same mechanism of action, vasodilation. He
16 testified yesterday that a person of ordinary skill in the
17 art would expect them to have the same effect as
18 treprostinil even though they're different drugs, even
19 though they're different routes of administration.

20 If Dr. Nathan can say that with respect to those
21 studies that he said failed, then when you look at Saggar,
22 which is the exact same drug, the exact same mechanism of
23 action, then clearly you'd be motivated to combine that even
24 if it was IV because it provides valid results that are
25 useful to a person of ordinary skill in the art looking to

1 improve on those studies.

2 The prior art and obviousness doesn't need to
3 change every single thing. You just have to have a
4 motivation to combine. We believe there is.

5 On expectation of success, Faria-Urbina and the
6 '793 and Sagar disclose the results that are claimed. They
7 disclose the results that are claimed. We believe the fact
8 that they literally disclose the results is an expectation
9 of success -- a reasonable expectation of success to get the
10 claimed outcome.

11 But there's more than that.

12 THE COURT: When you say they disclosed the
13 results, what's the best results that they disclosed?

14 MR. SUKDUANG: Sure. Two points on that.
15 Faria-Urbina Tables S3 and S4 are directed to --

16 THE COURT: Those are the -- like, three
17 patients and three patients; right?

18 MR. SUKDUANG: Correct. But the claim is only
19 directed to one patient. Faria -- and we're talking about
20 expectation of success, not anticipation. Although it
21 anticipates.

22 Faria-Urbina Tables S3 and S4, PH-ILD in
23 Table S3, PH-CPFE in Table S4, which are PH-ILD patients,
24 expressly disclosed six-minute walk distance. Dr. Nathan
25 said six-minute walk distance is exercise capacity. They

1 expressly disclose 21 and 55 meters respectively in increase
2 in six-minute walk.

3 That's Claim 17. That is literally disclosing
4 that. They have the same dosing. Dr. Nathan admitted
5 Faria-Urbina is the dosing of Claim 1.

6 With respect to '793, UTC admitted to the PTAB
7 and the FDA that the claims of the '793 are treating PH-ILD
8 patients to improve their exercise capacity. That's
9 Claim 1. '793 patent is the same dosing as Claim 1.

10 Those are the two pieces of evidence that
11 clearly disclose Claim 1 and Claim 17.

12 Saggar, again, although IV, discloses
13 improvements in six-minute walk. He disclosed Claim 5, more
14 than 200 picograms per milliliter of NT-proBNP. He
15 discloses the same magnitude of FVC.

16 THE COURT: So Saggar disclosed, I think it's
17 BNP; right?

18 MR. SUKDUANG: BNP. And Dr. Channick testified
19 and Dr. Saggar testified that BNP and NT-proBNP are just
20 measurements of the same thing.

21 THE COURT: Was that the testimony or was the
22 testimony more like NT-proBNP, whatever exactly it was, he
23 described it as like a sliver or --

24 MR. SUKDUANG: I think it's a precursor. I
25 can't remember, Your Honor, if BNP is the final or the

1 precursor. That could be one or the other.

2 THE COURT: The point is whatever his testimony
3 about that, it's pretty hazy.

4 MR. SUKDUANG: Yeah. I believe if you go back
5 to Dr. Saggar's testimony and, again, with Dr. Channick,
6 they measure this outcome, the BNP, the NT-proBNP, because
7 they tell you the same thing.

8 THE COURT: So you believe that somewhere in
9 Dr. Saggar's hour-plus of testimony he said BNP and
10 NT-proBNP measure the same thing?

11 MR. SUKDUANG: I think Dr. Saggar and
12 Dr. Channick because you actually asked Dr. Channick some
13 questions about what do you measure? Do you measure this?
14 And he said, "Our group at UCLA measures the BNP." But it
15 tells you the same thing, if I remember his testimony
16 correctly, he said it relates to some sort of peptide
17 produced when the heart isn't functioning a certain way.
18 You measure that as a measurement that you look for for a PH
19 or PH-ILD.

20 THE COURT: I guess what I'd say is in the
21 briefing you submit, it would be worthwhile for you to
22 persuade me that something that discloses BNP is good for
23 disclosing based on what a person of ordinary skill in the
24 art would understand.

25 MR. SUKDUANG: Absolutely, Your Honor. Thank

1 you for that direction.

2 Going back to expectation of success, if I can,
3 Agarwal, Parikh, Dr. Channick talked about that. You heard
4 from Tapson, you heard from Dr. Parikh, both authors of
5 Parikh 2016. You heard from Dr. Waxman about Agarwal.
6 Those all also provide a reasonable expectation of success
7 in achieving the limitations of the asserted claims because,
8 again, it's inhaled treprostinil. It's Tyvaso. Both of
9 them literally disclose the exact same dosing as Claim 1 in
10 the INCREASE study. They disclose improvements in various
11 outcomes including exercise capacity and six-minute walk.
12 Those are expectation of success documents that a person of
13 skill in the art would look at in the totality of the
14 evidence.

15 Dr. Rothblatt's 2018 earnings call also
16 relies -- she specifically said, "I talked to Dr. Waxman.
17 This drug works." That's expectation of success.
18 Dr. Rothblatt acknowledged that looking at posters and
19 presentations, and she used that word "UTC powered the
20 study" and she specifically said INCREASE and PERFECT. The
21 only posters and presentations related to Tyvaso and PH-ILD
22 are Agarwal, Parikh, Faria-Urbina. Those are the posters
23 Agarwal and publications, Parikh and Faria-Urbina, because
24 Dr. Nathan said everything else is other drugs. That
25 provides a reasonable expectation of success to a POA. And

1 that was well before the priority date.

2 You heard from Dr. Smith. He testified that the
3 reason why UTC did the INCREASE study is because Dr. Waxman
4 came in. He submitted his Agarwal abstract before it was
5 published, talked about it. Dr. Waxman testified after that
6 presentation the then-president of UTC said, "We're going to
7 do this study."

8 That's not only his testimony. It's reported in
9 documents from UTC. There's a proof-of-concept document
10 that Dr. Smith talked about and others. There's an
11 investigator brochure. There's presentations that Dr. Smith
12 generated internal consumption and external consumption
13 prior to 2020 that said -- pointing specifically to Agarwal,
14 that it is supportive evidence of Tyvaso in ILD.

15 THE COURT: One of the principles that I
16 remember is the route that the plaintiff took to inventing
17 the invention can't be used to show obviousness.

18 MR. SUKDUANG: And that's a very good point.
19 Dr. Smith didn't join INCREASE until after the protocols
20 were finished. He testified to that.

21 THE COURT: Yes.

22 MR. SUKDUANG: Dr. Peterson testified to that.
23 And the invention, they say, was the result. Dr. Waxman
24 came in 2015 before there was a protocol even in place and
25 brought this information.

1 And those presentations, Dr. Smith wasn't there.
2 He wasn't involved in this project at that time. And
3 Dr. Waxman's PowerPoint presentation back in 2015, which was
4 discussed with nobody who was an inventor at that time, made
5 UTC do this.

6 THE COURT: I think I understand what you're
7 saying, which is you agree with the principle I just said.
8 But you're kind of relying on Dr. Waxman and he's not part
9 of the invention process.

10 MR. SUKDUANG: None of the people who were at
11 that meeting were part of the invention process. None of
12 those people. UTC, a company, is not an inventor.

13 THE COURT: I understand that.

14 MR. SUKDUANG: Only individuals. And none of
15 the individuals, Dr. Deng, Peterson, Smith, had anything to
16 do with that 2015 meeting.

17 THE COURT: Okay. So all right. Yes, I
18 understand that.

19 MR. SUKDUANG: Going to Claims 1 and 17, we
20 talked about it briefly. What's the best evidence? It's
21 Faria-Urbina and '793 patent. I went through those with
22 respect to Tables S3 and S4 and UTC's acknowledgment. We
23 believe that the combination of Faria-Urbina and '793
24 renders obvious.

25 I know I'm going over my time, Your Honor. I

1 apologize.

2 THE COURT: That's all right. I think I said
3 yesterday it's at my discretion.

4 MR. SUKDUANG: With respect to Claim 14, again,
5 the '793 patent literally discloses a dry powder inhaler and
6 a dry powder formulation of treprostinil inhaled. You would
7 be motivated to combine that with Faria-Urbina that renders
8 Claim 14 obvious.

9 Counsel wants to point to your prior decision in
10 2022. This issue actually came up and you made judicial
11 findings. We argued that dry powder was not enabled and not
12 described in the '793 patent. They argued the opposite,
13 that as of 2006, a person of ordinary skill in the art could
14 more than easily enable a dry powder inhaler of treprostinil
15 and a dry powder formulation. We lost on that.

16 And now they had Dr. Nathan come up and say in
17 2020, two decades later or slightly less than two decades
18 later, no one would know how to do this. It's just not
19 credible, Your Honor, based on the '793 patent, based on the
20 disclosure of the '327 patent.

21 THE COURT: I thought of other reasons. I
22 thought -- I had my doubts about what Dr. Nathan was saying
23 about that and I believe that he was saying a medical doctor
24 wouldn't know how to do that. But I don't remember the
25 exact POSA definition, but clearly, other kinds of people

1 knew how to do that.

2 MR. SUKDUANG: Sure. And he acknowledged that.
3 But then how is the claim valid if people knew how to do it,
4 if UTC admitted that you can do this as of 2006? And that's
5 enablement. That's things outside of the spec of the '793.
6 How can UTC legitimately say in 2020 that a dry powder
7 formulation of treprostinil and dry powder inhalers, no one
8 knew how to do it.

9 In fact, we addressed this very issue in claim
10 construction. You remember the dry powder issue?

11 THE COURT: So just -- I don't remember claim
12 construction. But I guess what I'd say is you're citing to
13 a lot of things that are actually not part of the record of
14 this trial.

15 MR. SUKDUANG: No. The '327 patent is part of
16 the trial. That's in evidence.

17 THE COURT: Right. But you're saying three
18 years ago claim construction. Those things are not part of
19 the trial.

20 MR. SUKDUANG: I'm talking about claim
21 construction in this case on dry powder inhaler. Remember
22 there was a dispute -- the question was the claim
23 construction decision is not part of -- the claim
24 construction decision is not part of the trial. You are
25 correct. But the claim construction and the briefing is

1 part of the record. And UTC made arguments with respect to
2 dry powder inhaler pointing to the very provisions of the
3 '327 patent acknowledging that it was all out there. We
4 believe Claim 14 is obvious.

5 For Claim 5, we talked about Saggar. You asked
6 me some questions about that and we put that in the
7 briefing.

8 For Claim 6, it's exacerbations of interstitial
9 lung disease. Dr. Hill said if a patient is getting better,
10 there's no exacerbation. And further, the six-minute walk
11 distance, which is in Faria-Urbina, in Saggar, those are
12 evidence that Dr. Channick recognized show a -- such a weird
13 way to say it, but a lessening of the worsening. So they're
14 not getting worse. Exacerbation is getting worse, and
15 you're trying to reduce that.

16 For Claim 9, again, Saggar discloses FVC. It
17 discloses the same magnitude of difference with respect to
18 the INCREASE trial. And Dr. Wertheim actually provided
19 pertinent testimony, although in the context of written
20 description, that deals with obviousness. Dr. Wertheim
21 pointed to the absolute FVC data in the '327 patent and
22 talked about the 1 percent magnitude of difference. It
23 wasn't statistically significant, but he said you start
24 seeing a trend positively that leads to an expectation that
25 you would get statistical significance for absolute because

1 it was asked by counsel. Let's assume Claim 9 covers both
2 absolute and percent predicted.

3 For secondary considerations, Dr. Nathan had a
4 list of those things. They all really boil down to the six,
5 seven deadly studies.

6 THE COURT: I noticed that.

7 MR. SUKDUANG: A couple of points on that. One,
8 you have to -- for any secondary consideration, it has to be
9 the claims of the patent compared to the closest prior art.
10 He did not compare the claims of the patent to Faria-Urbina,
11 Agarwal -- excuse me. Faria-Urbina, '793, or Saggar. He
12 didn't discuss Agarwal and Parikh. He only compared them to
13 non-treprostinil, non-inhaled drugs. There's no nexus.

14 With respect to secondary consideration of
15 skepticism, doctors continued to do this. And as we talked
16 about with expectation of success and motivation, the papers
17 disclose the motivation and expectation to do this. There
18 wasn't skepticism.

19 With respect to --

20 THE COURT: It would be fair to say based on the
21 evidence that I heard at this trial that the topic was
22 controversial?

23 MR. SUKDUANG: It depends on who you're talking
24 to.

25 THE COURT: That would be sort of the definition

1 of controversy.

2 MR. SUKDUANG: And I think Dr. Waxman summed it
3 up, actually summed it up, and he was a little bit flippant
4 in his answer and I'm not trying to be flippant with you.
5 But he was asked questions about the riociguat trial, which
6 Dr. Nathan was a part of. He was asked: Did that stop you
7 from using Tyvaso in PH-ILD patients? And he said no. And
8 he was asked why. And he said, "Well, there are some very
9 narrow-minded clinicians out there that if you do anything
10 that's not on the label, you are wrong."

11 It's a little bit -- and I'm trying -- but
12 that's the plain matter-of-fact statement that those
13 things -- those studies did not dissuade individuals from
14 moving forward.

15 THE COURT: One thing I thought I heard early in
16 the case but then later on I started to think maybe I
17 misheard or misunderstood. Riociguat, what's the active
18 ingredient in that?

19 MR. SUKDUANG: Riociguat is the active
20 ingredient and the trial is called RISE-IIP.

21 THE COURT: Trial called -- riociguat, that is
22 not some form of treprostinil?

23 MR. SUKDUANG: It is not.

24 THE COURT: Okay. Thank you.

25 MR. SUKDUANG: And I believe it's oral as well.

1 And in terms of secondary considerations, again,
2 the nexus, the '793 is the nexus. UTC argued that to the
3 PTAB. That's earlier issued. The '327 patent cannot be the
4 nexus with respect to any objective indicia. UTC beats this
5 constant drum about these failed studies. We talked about
6 that.

7 The other argument with respect to obviousness
8 is that Faria-Urbina and Saggar were not actually PH-ILD
9 patients. They were PAH patients. That's what Dr. Nathan
10 testified to yesterday and today. And he said in order to
11 determine whether someone is a PH-ILD, you need right-heart
12 catheterization and high-resolution CT scans. And you need
13 to look at both and you need to look at the scans to make a
14 diagnosis.

15 Dr. Nathan testified based -- just looking at a
16 paper with no scans that none of these patients were PH-ILD.
17 And he agreed he was making a retrospective diagnosis on a
18 paper. He cannot say that they were wrong in their
19 diagnosis without having the evidence.

20 And when you look at Faria-Urbina and Saggar,
21 and when Mr. Davies took Dr. Nathan to it, those -- both of
22 those references say there was right-heart catheterization,
23 there was higher resolution CT, and both references say both
24 were looked at to make a diagnosis.

25 They're not disclosed in the paper, of course,

1 because they're giant, high-resolution images. Dr. Nathan
2 tried to present some images to you, and they -- one
3 diseased lung. You said, Is that a healthy lung? He said,
4 No, that's a diseased lung so these -- so these images
5 printed don't make any difference.

6 The fact of the matter is, Dr. Waxman, who was a
7 member of the INCREASE study, knows how to diagnose. He had
8 these data that Dr. Nathan said. He looked at them when
9 making the diagnosis. A retrospective study is not looking
10 back and making a rediagnosis. It's looking at the patients
11 who were diagnosed, treated prospectively, as everybody said
12 in these papers were, and then you have data and then they
13 look at, well, what does this data teach us.

14 Even though I wasn't running a clinical trial,
15 what did I learn from this? That's a retrospective study.
16 And Dr. Thisted drew this barn and he said -- and I think my
17 counsel called it the --

18 THE COURT: We don't need to talk about
19 Dr. Thisted.

20 MR. SUKDUANG: Sure.

21 With respect to the PH-ILD patients, we believe
22 they're PH-ILD patients. There's no evidence to establish
23 they were not.

24 And then Dr. Waxman testified that, Are the
25 patients in Faria-Urbina the same as INCREASE? UTC asked

1 him that. He said, Pretty much the same. That's enough for
2 obviousness.

3 Finally, on page 888 -- 881 of the transcript
4 from yesterday, Dr. Nathan was asked: "What does it take to
5 do a Phase 3 clinical trial? What would a company need?"

6 And he said this on page 881, line --

7 THE COURT: I kind of remember a long answer.

8 MR. SUKDUANG: It's a very short answer, this
9 part. He said they need -- the question was long. The
10 answer is: "They need some kind of pilot data or proof of
11 concept that they have a shot at a successful clinical
12 trial." That was his answer. Pilot data, proof of concept.

13 Dr. Nathan and UTC believes Faria-Urbina, '793,
14 Sagar are not pilot studies and are not proof of concept.
15 We disagree. If you take Dr. Nathan as true, UTC conducted
16 a clinical trial that was tens of millions of dollars based
17 on zero evidence and just on a hunch.

18 Dr. Nathan said that would never ever happen.
19 And Dr. Nathan never pointed to any document that disclosed
20 treprostinil in an inhaled route in PH-ILD except for the
21 prior art that we asserted. Everything he pointed to were
22 drugs of a different context.

23 THE COURT: The Federal Circuit has said, I
24 think, in various contexts, that the fact that a clinical
25 trial happened doesn't prove either reasonable expectation

1 of success or motivation to combine.

2 MR. SUKDUANG: I believe there are cases that
3 say if you run a clinical trial, that might not be enough
4 for reasonable expectation of success or motivation to
5 combine.

6 But what UTC is saying is that here they're
7 saying the exact opposite. They're saying you cannot have a
8 motivation or a reasonable expectation of success without a
9 Phase 3 clinical trial. That was the very last piece of
10 testimony -- or in the middle of cross-examination for
11 Dr. Nathan.

12 Mr. Davies asked him --

13 THE COURT: So that's pretty much a -- I mean,
14 that's practically a legal question. And I did hear
15 Dr. Nathan say that. And I think he's -- you know, he said
16 in this specific case, that's the way it shook out.

17 MR. SUKDUANG: Correct.

18 THE COURT: So he wasn't making a general
19 principle statement. But I don't expect him to spend a lot
20 of time reading Federal Circuit cases.

21 MR. SUKDUANG: No. But here, Your Honor, all
22 you're required to have is a motivation and an expectation
23 of success. We're looking at the prior art that is not
24 around the subject matter, and the subject matter is here.

25 We're looking at prior art that is the subject

1 matter. Dr. Nathan admitted the dosing is the same in
2 Faria-Urbina. He admitted that it's Tyvaso.

3 His dispute is whether it's PH-ILD or not. But
4 he admitted that the data is the data. The six-minute walk
5 data for exercise capacity is there. The data in Saggar was
6 there. He's not disputing that the data is there.

7 The fight is whether these are PAH patients or
8 not or PH-ILD patients or not. And looking at the string of
9 evidence in this area, there's ample motivation and
10 expectation to render the claims invalid.

11 I'd like to move on because I don't want to take
12 up more than I need.

13 THE COURT: Yeah, and I want to make sure just
14 because I would like to be over by 1:00 and --

15 MR. SUKDUANG: Yes, I apologize.

16 THE COURT: Sorry about that.

17 So try to wrap up pretty quickly.

18 MR. SUKDUANG: Two more topics and I'll keep it
19 short.

20 THE COURT: Keep it short.

21 MR. SUKDUANG: Prior sale. I'm going to talk
22 about Claims 1 and 17, Your Honor.

23 The record is clear. Tyvaso was sold as of
24 2009. The record is clear. Doctors treated PH-ILD patients
25 with Tyvaso. The record is clear. They used the dosing on

1 the 2009 label. They went up to 12 breaths. The record was
2 clear on that. And they observed improvements in the
3 exercise capacity, both by six-minute walk and observational
4 data.

5 There was a sale of the drug. Dr. Saggar and
6 Dr. Hill testified that they had rejections of Tyvaso in
7 this patient population and that they had to write appeals
8 to get those prescriptions approved. Dr. Nathan went into
9 more detail than Dr. Saggar, but Dr. Nathan testified --
10 excuse me, Dr. Hill.

11 THE COURT: I remember that.

12 MR. SUKDUANG: Yes. But he'd write a
13 prescription, it'd get rejected. Even though PAH was on
14 there, it still got rejected because it was a ILD patient as
15 well.

16 Under Dr. Nathan's opinion, if it said PAH,
17 there should be no rejection because it's approved for that
18 indication. But the fact that prescriptions were rejected
19 shows that doctors were writing scripts, insurance companies
20 knew it and, ultimately, approved it because the doctors
21 convinced them that this was the correct drug for this
22 patient population.

23 UTC's counter to the actual commercial sale is,
24 one, it's not public. Prescribing information is private.
25 Prior sale does not require a public sale. That's the

1 *Helsinn* case from the Supreme Court.

2 They argued second that UTC did not make the
3 sale. Prior sale doesn't require UTC's commercial sale. It
4 just requires a commercial sale. And Tyvaso was never sold
5 by UTC directly to patients. It's always through the
6 specialty pharmacy.

7 THE COURT: Right. So I think that's the law,
8 that the pharmacy making a sale counts as a sale --

9 MR. SUKDUANG: Correct.

10 THE COURT: -- but that would be a good thing to
11 have a case citation in your brief.

12 MR. SUKDUANG: Yes.

13 There's a commercial sale. It doesn't need to
14 be public. It doesn't need to be UTC. Dr. Nathan agreed
15 that it was on sale since 2009. And the record is --

16 THE COURT: So one other question I have about
17 the commercial sale is really for both of you.

18 Is -- let's say the pharmacy is making the sale.
19 The sale by itself is not practicing the method. Does -- is
20 there a law that says -- because I never had this come up
21 before -- that a commercial sale -- what's required if
22 there's a commercial sale of something which is a commercial
23 sale and then -- and where there's a prescription written
24 and then a doctor goes off and treats PH-ILD with it?

25 What's needed to connect those two things that

1 will make that an anticipatory commercial sale?

2 MR. SUKDUANG: Sure. So for the commercial sale
3 prong of prior sale, there just needs to be a sale of the
4 device or product, in this case Tyvaso, that would lead to
5 the method. And we have cases. And I apologize --

6 THE COURT: So that's one other thing, that it
7 will be useful to have a case. And that's something I don't
8 know. So if that's an issue, and it didn't seem to be an
9 issue the way the parties treated it at trial, but sometimes
10 I think of issues that are not issues, I would like to have
11 a case that says what you just said.

12 MR. SUKDUANG: And then the tying together part
13 of your question.

14 In the prior sale context, if it's a method,
15 just selling the product, you're right, doesn't practice the
16 method, it's just the product that you use to do it. And
17 there are cases out there that that happened and nothing
18 else happened and that that was enough for the commercial
19 prong.

20 Here, we have additional steps, as you pointed
21 out. The first step was that there was a prescription for
22 the intended use.

23 THE COURT: Let's skip over to -- what's the
24 last topic that you wanted to address?

25 MR. SUKDUANG: Do you want me to cover ready for

1 patenting on the prior --

2 THE COURT: No, I'm not really interested in
3 that.

4 MR. SUKDUANG: Sure. The last issue I want to
5 cover, Your Honor, is what we briefed earlier. And this is
6 the -- we don't believe validity needs to be addressed at
7 all with respect to the pending claims.

8 Dr. Nathan's testimony is clear. He
9 testified -- I'll summarize without the slide.

10 Dr. Nathan testified that the claims are
11 directed to the intended result of practicing the method of
12 Claim 1. He testified that you do not need to measure any
13 element in 5, 6, 9, or 17 for infringement. And Mr. Carsten
14 recognized that on infringement.

15 He testified that if you infringe Claim 1, you
16 automatically infringe the dependent claims. That means
17 there's nothing in those dependent claims that you need to
18 do to infringe. If that's the case, then under the law, and
19 we'll brief this, the claims are directed to an intended
20 result of Claim 1. And that's what he said clearly and
21 unambiguously.

22 If they're directed to an intended result and
23 you don't need to do anything for infringement, they're not
24 entitled to patentable weight, and therefore, if Claim 1 is
25 invalid, those claims are also invalid because they cannot

1 be rested upon for patentable weight to try to avoid
2 invalidity if Claim 1 is found invalid.

3 THE COURT: So it's interesting that you bring
4 that up because the format of these claims, at least some of
5 them, have bugged me since I first learned about them.

6 But my question is: Isn't this a claim
7 construction issue that should have been brought up long
8 ago?

9 MR. SUKDUANG: No, Your Honor. Because
10 regardless of the construction, Dr. Nathan is taking the
11 view -- and again, his position is --

12 THE COURT: But he's interpreting the claims.

13 MR. SUKDUANG: And he's interpreting the claims
14 in order to assess infringement and validity. That is UTC's
15 position. And if you take their position as true for
16 infringement, for infringement, that you don't need to do
17 any of these things, and that's the only way they can win,
18 because, as I went over, it's not done.

19 They can only win by saying you don't need to
20 measure these outcomes, you just know they happen. If that
21 is their position on infringement, they cannot, as
22 Dr. Nathan tries to do, say that you need to prove each of
23 these elements for invalidity, that you need to show with
24 concrete proof.

25 That is not a claim construction issue. That's

1 a different interpretation of invalidity and infringement.
2 Not a burden issue either, not a preponderance or clear and
3 convincing. It's simply, what do I need to prove for the
4 claim? We understand our burden and they understand theirs.

5 If you adopt Dr. Nathan's position on
6 infringement, those claims cannot be used to keep the patent
7 valid for validity because you can't have it both ways. You
8 can't have a dependent claim --

9 THE COURT: All right. I get what you're
10 arguing here. It's something that's going to be briefed so
11 I don't think it's helpful to keep talking about it. And I
12 want to make sure that I give Mr. Carsten enough time. So
13 thank you.

14 MR. SUKDUANG: Thank you, Your Honor. I
15 appreciate the time and Liquidia appreciates your time.

16 THE COURT: All right. And, Mr. Carsten, don't
17 feel obligated because I know I said I want to end at 1:00.
18 I don't want to cheat you out of a fair response.

19 MR. CARSTEN: I'll try my best, Judge, although
20 I'll say I was little nervous when you did say that.

21 I'm happy to pick up wherever Your Honor would
22 like. I guess on that last point I think, candidly, that
23 that's an issue that will come up in the context of
24 post-trial briefing.

25 But I would just say on that point briefly, we

1 rely upon the INCREASE trial to demonstrate as evidence for
2 infringement purposes that these therapeutic effects are
3 happening and are more likely than not to happen. And
4 that's a different sentiment in kind from what we've heard
5 the argument, which was that they have no patentable weight
6 and they don't matter.

7 It's a very different aspect. And I think, you
8 know, the law is pretty clear that you can meet your burden
9 on infringement by pointing to evidence -- by a
10 preponderance of the evidence and they have to prove their
11 invalidity positions by clear and convincing. And so I
12 think that's where the difference lies here. Same
13 construction, same material, but it's a different analysis
14 for infringement than invalidity.

15 But I think that will be briefed in the context
16 of the post-trial briefing.

17 THE COURT: I'm satisfied with that.

18 MR. CARSTEN: Thank you, Your Honor.

19 I think I'd like to start where you spent the
20 bulk of your time with Mr. Sukduang, if I may, and that's on
21 the obviousness case.

22 THE COURT: I think he spent the bulk of his
23 time on it.

24 MR. CARSTEN: Your time together, shall I say.

25 THE COURT: Fair enough.

1 MR. CARSTEN: Mr. Smith, could I have the slide
2 PDX 8.10. And I'll pick it up with, I think, the simple
3 punch line, and that is that the '793 patent, which is
4 instrumental to each and every one of the combinations that
5 Your Honor heard about for every of the six claims, is not
6 prior art.

7 THE COURT: Well, I mean, if that turns out to
8 be true, yeah, then that's all gone.

9 MR. CARSTEN: Right. And so it is case
10 dispositive for Claim 14. And in terms of whether or not
11 the patent -- the '793 patent is prior art under 102(a)(1),
12 the effective filing date, the priority date, is April 17 --

13 THE COURT: So I don't think it's worthwhile to
14 argue this now because I'm going to -- I'm not going to
15 grant your motion today or any time until I've got this
16 briefed. So why don't you go on to assuming that it is
17 actually prior art.

18 MR. CARSTEN: Okay. Assuming that it is prior
19 art, then, the combination here makes little sense.
20 Mr. Sukduang did his best to sort of provide a rationale for
21 why these would be combined.

22 But really what you have is Faria-Urbina, which
23 is a nebulized liquid inhaled product. They say, I'm going
24 to take that and its method and then I'm going to combine it
25 with a disclosure that has to do with hemodynamic data, that

1 has the disclosure for a dry powder in the claims, and then
2 I'm going to combine those to make a new product which is a
3 dry powder product and I'm going to expect that the results
4 of administering that product with the nebulized method is
5 actually going to give me results that are same as or better
6 than an injectable reference from five years prior. It just
7 doesn't add up.

8 The one thing that the experts did agree upon
9 here is that clinical trials and medicine are unpredictable
10 arts and you do not have an expectation of being able to
11 expect what's going to happen between these various
12 formulations. So when you apply the same chemical compound,
13 the same drug, active ingredient by virtue of these
14 different routes, Dr. Nathan, Dr. Channick, all of them said
15 you can't predict what's going to happen. All you can say
16 for sure is it's not going to be the same.

17 So that that's the real missing link in terms of
18 this Frankenstein combination of the three references, if
19 you'll have it.

20 Here's a sample. So Dr. Channick said there are
21 different products and we already talked about this. We
22 can't say one is going to behave the same as the other.
23 It's a different formulation. And we know this based upon
24 the real-world experience of UTC. Remember, UTC had Tyvaso
25 approved in 2009 and then it developed the dry powder

1 product much later in 2022.

2 In order to establish that, in order to get that
3 dry powder product approved, the FDA required clinical
4 trials because it wasn't the case that there was --

5 THE COURT: The requiring -- again, what the FDA
6 said is different than the standard for patentability.

7 MR. CARSTEN: I agree with you, Your Honor. It
8 certainly is different. The FDA can require things beyond
9 or below a standard for reasonable expectation of success or
10 motivation to combine. I agree with that.

11 THE COURT: They have to be satisfied --
12 generally speaking, my impression is the FDA has a much
13 higher standard for approving something than the Patent
14 Office. That's not saying something bad about the Patent
15 Office. It's saying that the standard for patentability
16 often doesn't require any proof that the thing will actually
17 be, among other things, commercially sellable.

18 MR. CARSTEN: You find -- I guess my point on
19 this, Your Honor, is not about the standards necessarily.
20 But if people skilled in the art, if folks in industry
21 believe that these two different routes of administration
22 would behave the same or would behave similarly, that's
23 inconsistent with requiring additional safety and efficacy
24 data from UTC in order to transfer over to a dry powder
25 product.

1 I don't want to overstate it. But I do think
2 it's a relevant point and undercuts the positions you're
3 hearing that people would just willy-nilly be motivated
4 these different doses and then expect that an injectable
5 systemic results are going to be obtained but better by
6 virtue of this other inhalation.

7 That just doesn't make any sense. I think you
8 heard some compelling testimony pointing out that really is
9 not the way that people of ordinary skill in the art would
10 behave in this area.

11 THE COURT: One of the things that I heard from
12 your opponent that I wasn't thinking about was that
13 Dr. Waxman -- the idea or that argument of the defendant is
14 Dr. Waxman more or less voiced the idea that this is
15 something that should be tried back in 2015. What's your
16 response to that?

17 MR. CARSTEN: I guess a couple of responses,
18 Your Honor. One, they are not pressing an inventorship
19 defense --

20 THE COURT: I understand. But in terms of
21 real-world evidence about motivation to combine or
22 reasonable expectation of success, isn't this useful --
23 isn't Dr. Waxman's thoughts about it useful?

24 MR. CARSTEN: Well, I think Dr. Waxman -- none
25 of us were in the room between Dr. Waxman and Dr. Rothblatt

1 at UTC to see exactly what was disclosed and what was
2 shared.

3 THE COURT: We have evidence in the record of
4 some sort.

5 MR. CARSTEN: There was a meeting and the
6 evidence in the record that we have is the data from the
7 Faria-Urbina paper. That's Dr. Waxman. He's the lead
8 author. And you heard testimony surrounding that data from
9 both Dr. Thisted and Dr. Nathan suggesting that people of
10 ordinary skill in the art --

11 Now, mind you, I found Dr. Wertheim really
12 arresting at one point when he came in here and was asked,
13 what did you do to prepare? And he said there's going to be
14 some superstars, the star power in this room is going to be
15 incredible. So I want to read hundreds and hundreds of
16 papers. I want to be as educated as they are.

17 The people we're hearing from about the
18 off-label use, they were the luminaries. They were the
19 experts in the field. They were not people of ordinary
20 skill in the art.

21 THE COURT: I assumed Duke and UCLA and Mass
22 General, those are leaders in the field.

23 MR. CARSTEN: Exactly. So the question is:
24 What did the Faria-Urbina paper teach to people of ordinary
25 skill in the art? And you heard from Dr. Thisted in terms

1 of the statistical analysis, from Dr. Wertheim in terms of
2 his appreciation for it, and Dr. Nathan that when you
3 actually press into that, there really is no "there" there.
4 Even Dr. Channick admitted that with a low end number that
5 we have in Faria-Urbina, that those things have to be taken
6 with a grain of salt.

7 And we also know that the Faria-Urbina paper as
8 well as other information that my learned friends have
9 pointed to emphasized the notion -- as well as review
10 articles emphasize the notion that, gee, maybe ILD isn't the
11 right patient profile here. Maybe it's COPD. COPD seems to
12 be better.

13 And when you look forward and you look at the
14 studies that were actually done, this is a study on
15 treprostinil. It is an inhalation study. It is COPD, which
16 everyone thought or at least seemed to think at the time was
17 the golden child among Group 3. And that failed. That was
18 the PERFECT study.

19 So I think that the real-world data here, if
20 you're going to look at that, demonstrates -- and I think
21 Dr. Wertheim did a great job of explaining this. I've got
22 seven mountain climbers ahead of me and they all died.
23 That's not exactly motivation to go up and try again. It
24 actually makes it even less obvious to go ahead and try
25 again.

1 THE COURT: I think in the mountain climbing
2 world, that's extra motivation to go up.

3 MR. CARSTEN: I would not be a person of skill
4 in the art in that world then. I hope I answered your
5 question. I'm not entirely sure I did.

6 THE COURT: So we're talking about Dr. Waxman
7 and Faria-Urbina. I guess, I mean, in some ways one of the
8 answers you've given is that the people that the defendant
9 was pointing to as prescribing Tyvaso to PH-ILD patients
10 were -- Judge Connolly has a word for this, but "super
11 POSAs."

12 MR. CARSTEN: I've heard that.

13 THE COURT: That may not be his word. But I
14 heard him talk about this, that these people are not persons
15 of ordinary skill in the art. They weren't back at that
16 time and so they're actually the wrong reference group.

17 MR. CARSTEN: And I think there's a fair bit of
18 that going on here, Judge. It made it seem almost as if
19 everyone in the world was out there prescribing this off
20 label.

21 THE COURT: I get that, in fact, because I saw a
22 number of places that said it was not widespread. And at
23 the time I was seeing that, I was thinking that's indication
24 it's actually happening.

25 But in terms of -- and, in fact, I remember

1 because Dr. Wertheim, who I think said he started in 2014;
2 Dr. Parikh, who was a fellow in 2016, these younger, newer
3 people seem to be -- they seem to say "I'm not really
4 hearing about this," but they were barely POSAs at the time.

5 MR. CARSTEN: They were POSAs at the time. I
6 think Dr. Wertheim said, yeah, I qualified under either
7 one --

8 THE COURT: I wasn't sure whether Dr. Parikh was
9 or wasn't.

10 MR. CARSTEN: I don't recall if he
11 qualified under the parties' --

12 THE COURT: We don't know enough about his
13 background, I think.

14 MR. CARSTEN: I think we could find that out for
15 sure and it may actually be in the record.

16 THE COURT: If it's not in the record, it
17 doesn't count.

18 MR. CARSTEN: But my point is really the
19 question isn't, what did Dr. Rothblatt extract?
20 Dr. Rothblatt, she's not an M.D., she's not a person of
21 skill in the art. But she spent her life around developing
22 treatments for pulmonary hypertension, so she's quite
23 knowledgeable.

24 The question is what she derived and whether she
25 was motivated or inspired to carry forward. The question is

1 who was a person of skill in the art? What was Dr. Wertheim
2 motivated to do based upon Faria-Urbina? And that evidence
3 is crystal clear and that is nothing.

4 You heard Dr. Wertheim. I wouldn't do it. I
5 prescribed Tyvaso for PAH and PAH only. That was the state
6 of the art. That was the evidence. And why --

7 THE COURT: Well, that kind of actually makes
8 sense because if you're two years attending physician,
9 whatever, and you prescribe things off label and the
10 patients end up dying, you're probably going to have to get
11 a new job, whereas --

12 MR. CARSTEN: I think you won't be practicing in
13 three years.

14 THE COURT: -- whereas the people we've heard
15 from in the trial, the Dr. Channicks and Nathans of the
16 world, you know, they can kill a few people and they're
17 still going to keep on going.

18 MR. CARSTEN: Yes, Your Honor. But you get my
19 point, I think, and that is --

20 THE COURT: Not a point that I thought of before
21 you brought it up.

22 MR. CARSTEN: It's not -- yeah, I think there's
23 been -- we pointed to the seven deadly studies and there
24 have been comments about, well, are they deadly or aren't
25 they, and all this other stuff about them.

1 You know, I think where I come down on this,
2 where I land on this one, Judge, is, you know, these seven
3 deadly studies, maybe not all of them killed people, but,
4 man, this is a very vulnerable patient population. These
5 are people who are going to die.

6 THE COURT: Yeah, I've heard that.

7 MR. CARSTEN: And then, two, even if the -- with
8 RISE-IIP, you heard the story from Dr. Nathan about how he
9 spent the three days in Europe going through CT scan after
10 CT scan trying to figure out what happened here and what
11 caused this problem.

12 You know, I think if not killing people -- if
13 not deadly in that sense, you've heard about the nihilism
14 that surrounded this. It killed the motivation to climb the
15 mountain further. That's the seven deadly studies.

16 And so with that, I mean, I think there's no
17 motivation to combine these disparate references and have
18 any expectation that you're going to mirror and better an
19 injectable result.

20 Remember, the only FVC that went up in this case
21 that you heard about was from the Saggar 2014 paper.
22 Everyone else went down, down, down, and that's bad. And
23 that Saggar reference, the p-value was like .687.

24 I mean, that's -- and to say, okay, I'm going to
25 start with an inhaled nebulized and then convert it to a dry

1 powder and expect I'm now going to turn around and get these
2 FVC values that go up, that's outrageous. That's not what a
3 person of skill in the art would expect. That's not what
4 Dr. Wertheim would expect.

5 And so I don't believe that they've met their
6 burden by clear and convincing evidence on any of these,
7 even assuming that the '793 patent stands, which it ought
8 not.

9 And as a separate minor measure, I've been doing
10 this a while, not as long as you, Judge, but a while, and
11 I've never --

12 THE COURT: I hope you haven't been doing it
13 longer than me.

14 MR. CARSTEN: -- and I've never seen on direct
15 examination somebody point to the '327 patent in order to
16 justify or credit a teaching from the prior art to explain
17 why it's relevant.

18 You pointed out earlier, Judge, Section 103,
19 which has the manner of the patentee's invention shall not
20 be used to invalidate the patent. We have that expressly.
21 The man looked -- Dr. Channick looked expressly at INCREASE
22 data to justify the importance and relevance of the Sagar
23 2017 FVC data. I mean, that's expressly using hindsight.
24 No doubt about it.

25 THE COURT: Whatever it is that you're referring

1 to, I didn't catch it while it was happening, assuming your
2 memory of it is correct. So to the extent that that's an
3 issue about anything that's occurred in the trial, that's
4 something you should bring up in your briefing.

5 MR. CARSTEN: Yes, Your Honor, we certainly
6 will.

7 Just a few moments to go, and I'd like to spend
8 a little bit of time on each of the other three defenses
9 very briefly, if I might.

10 THE COURT: Yes.

11 MR. CARSTEN: If we could go, Mr. Smith, to
12 PDX 8.5.

13 And this is the so-called prior sale defense. I
14 mean, we talked a little bit about this. You remember they
15 had a prior use defense. And then that was stricken because
16 it was waived or it hadn't been raised in a timely manner.

17 THE COURT: Right.

18 MR. CARSTEN: And then it was -- what they did,
19 essentially, was repackage that prior use defense. Of the
20 prior sale defense, I would say that 95 percent of the
21 evidence that went in had to do with use, not sale.

22 THE COURT: Yeah, but the use is related to why
23 the sale might be a commercial sale to --

24 MR. CARSTEN: I'm not saying that -- if I were
25 trying the case on their side, I probably would have chosen

1 the same tactic; right? I mean, it makes sense why they
2 chose to introduce the evidence, and it is relevant in some
3 sense, the prior sale, and it gives context there.

4 I'm not suggesting that anything improper
5 happened, but I am pointing to the quantum of evidence that
6 really has nothing to do with sale, but really is about use.
7 And in order to qualify as a prior sale, you need a
8 commercial sale of the patented here method.

9 And so Your Honor asked my learned friend a
10 question earlier, what do you do when you have a situation
11 where you have a product and, you know, it's available
12 for -- it's capable of being used in a couple of different
13 ways and you have a patent case?

14 You asked in the context specifically of ANDAs,
15 and I don't think I have a case in hand for that --

16 THE COURT: I don't think it would make any
17 difference if it was a non-ANDA.

18 MR. CARSTEN: I don't think it would, but in the
19 event that it might, I'm going to certainly be scouring the
20 Westlaw for one.

21 But I do have a case called *BASF*, which says
22 that when you sell a product that can be used for multiple
23 uses and you're not giving guidance or advice on the one use
24 that's claimed, that doesn't count. That's not enough.

25 Because you -- the question isn't whether you're

1 selling the product that could be used for that. The
2 question is, are you selling the actual -- something that
3 embodies the method itself? Are you selling the method?
4 And so I think the *BASF* case stands for that proposition,
5 and we're happy to brief that.

6 But just very briefly on this, we don't think
7 there was evidence of a sale at all in the sense of a clear
8 and convincing level of evidence for a sale.

9 THE COURT: If I had to say, I think I heard
10 enough evidence to be convinced that there were pharmacies
11 that were filling out Tyvaso prescriptions where the doctors
12 had written them to treat PH-ILD.

13 I understand there's no specific sale that's
14 been identified, but I just don't think that's necessary
15 given the number of different doctors that I heard who, as
16 we've talked about as "super POSAs," that they were
17 prescribing it for this purpose following the 2009 label
18 dosing regimen and that the patients weren't getting this
19 for free.

20 So as a factual matter, I think I'm going to
21 find that there were sales. There may be things on the
22 periphery that mean they're not sales that count, but I
23 think there were sales by pharmacies for sure.

24 MR. CARSTEN: Okay. I understand. And thank
25 you for sharing that. I'm going to do my best to try to

1 disabuse you of that notion, of course, but perhaps not in
2 the next five minutes.

3 But I'll say there is record evidence that not
4 every ILD patient had PH. In fact, I think Dr. Channick
5 agreed with me that upon presentation or diagnosis,
6 there's -- quoting a Dr. Nathan paper -- about 8 to
7 15 percent of patients who were diagnosed with ILD have PH.

8 So just checking boxes doesn't say, according to
9 the Court's claim construction --

10 THE COURT: I'm thinking of Dr. Hill who is a
11 person who I'm sure was telling the truth to the best of his
12 ability who said he's done a couple of dozen of these over
13 the years. You know, so even if one patient was
14 misdiagnosed, that's a couple of dozen minus one.

15 MR. CARSTEN: But he also said that each one of
16 those patients had involved some PAH and that typically he
17 would check the box for PAH on the form that was sent into
18 the insurers.

19 And so the sale, we submit that there isn't
20 clear and convincing evidence that the sale was for PH-ILD
21 in terms of the transaction. In fact, you heard Dr. Saggart
22 say, yeah, we didn't have much challenge because we would
23 tick the box that said PAH.

24 And you heard Dr. Waxman saying, yeah, thank
25 goodness when this got approved for PH-ILD, I could put down

1 the right diagnosis to get this approved.

2 THE COURT: I think Dr. Waxman also said
3 something about generous payers, which I certainly
4 interpreted to be referring to people who were letting --
5 reimbursing him for off-label use.

6 MR. CARSTEN: That's the earnings call with
7 Dr. Rothblatt from UTC. And in that context, she said,
8 thanks to the kindness of generous payers --

9 THE COURT: He said that somewhere -- I thought
10 he said that. Well, maybe I'm confusing it. I thought
11 Dr. Waxman had actually said that, maybe in his speech to
12 the John Vane Society.

13 MR. CARSTEN: Well, referring to the
14 Dr. Rothblatt statement, she said, "Thanks to the kindness
15 and generosity of payers, we've been able to -- some Group 3
16 patients have been able to see benefit."

17 And so that's not saying that the payment, that
18 the prescription, the reimbursement was specifically for
19 Group 3. It just so happened that maybe it was done under
20 the PAH label and the group -- it was a Group 3 patient who
21 happened to see benefit from that transaction.

22 And so this is their burden by clear and
23 convincing evidence. I get they've got a number of these
24 super POSAs, to use your term, or whatever you credit it to,
25 who are out there saying they've done it, but in almost

1 every case or every case that I can recall there was always
2 a suggestion these people had PAH, or at least the insurance
3 company, that the person who was doing the buying,
4 understood it was for PAH.

5 And so I submit that even if you're going to
6 say, yeah, I'm convinced that there were commercial sales, I
7 think you need to go a step further, and I don't think that
8 they've tied that up with a bow.

9 I think it could have been something that they
10 could have done with a patient record, with a transaction,
11 with something that clearly established back before April of
12 2020 that they've actually done it. But that's their burden
13 and they never did. And it's a dearth of documentary
14 evidence there.

15 Moreover, I think it's -- this is an
16 anticipation flavor. And so when you look at -- remember,
17 they said as of 2009, I started doing this. 2009, the only
18 approved indication was PAH, you've heard that ad infinitum.

19 But in terms of the dosage, the label says you
20 can -- if three breaths are not tolerated for your first
21 dose, you can reduce to one to two breaths. That means that
22 the approved indication on the label, the approved dosage,
23 was a range from 6 micrograms to 54 micrograms.

24 That is different than the patent claim which
25 requires at least 15 micrograms up to a maximum tolerated

1 dose. And under the Court's -- well, this is a little bit
2 inherent anticipation argument. But understanding it's
3 pharmaceuticals, if you're relying upon a method for
4 inherent anticipation and the methods differ, there's no
5 inherent anticipation.

6 And so --

7 THE COURT: Sales of pharmaceuticals, I had a --

8 MR. CARSTEN: I'm citing your case to you,
9 Judge. Yeah, I've done that a fair bit today. I did it
10 with the --

11 THE COURT: Well, it's hard to say. You know, I
12 had a BASF case, but I don't think it was the BASF case you
13 cited. So the names of these people, particularly in the
14 pharmaceutical field, you know, you see the same names over
15 and over again.

16 MR. CARSTEN: Understood.

17 I want to move forward to the clinical -- the
18 DTX 008 anticipation very briefly. I think this falls apart
19 in the same reason, the salient case that I mentioned to
20 you, and that is, you know, Dr. Channick stood up on direct
21 and said, oh, it's the same dosing schedule, and then we
22 walked through it with him and it was not the same dosing
23 schedule as well.

24 And I also --

25 THE COURT: So we're talking about protocols

1 now?

2 MR. CARSTEN: Yes, the protocol. You call it
3 the protocol. We call it DTX 8. They call it the INCREASE
4 trial. Whatever. We're all talking about the same thing.

5 THE COURT: Yeah, yeah, yeah, but calling it DTX
6 is the least helpful way of reminding me of what it is.
7 I've got it now.

8 MR. CARSTEN: Okay. He said, well, it's the
9 same in terms of the dosing schedule. And we walked through
10 it and, no, it was not at all. He admitted, it's not the
11 same dosing schedule. And it's a different patient
12 population.

13 Now, the testimony that came in seemed to
14 suggest, well, at least Liquidia wants you to say, yeah,
15 this is -- it's a subset of the population that went in and
16 they would have experienced more benefit. But Dr. Channick
17 admitted that on the protocol that was not run, the DTX 8,
18 what they call the protocol, whatever, there is a carbon
19 monoxide diffusion limitation for the pollution criteria.
20 And in INCREASE there was an important FVC limitation where
21 the included patients had to be greater than or equal to 70
22 percent under FVC. Remember that one big blow and the
23 percent. There's no evidence that people in that -- would
24 have been here would have actually made it into the patient
25 population.

1 And the one thing we know from a different
2 dosing regimen and a different patient population is
3 unpredictable results. Dr. Channick said it himself. I
4 mean, the differences that we described in direct, with a
5 different patient population, you agree the results would in
6 fact be different from the results observed in the INCREASE
7 trial.

8 I can't predict the results. They may or may
9 not. I don't think anybody can say that they would have
10 exactly the same results.

11 So we have a salient situation, which is a
12 different method on a different patient population. And
13 then we've got the uncertainty surrounding what would happen
14 had that hypothetical clinical trial ever got run. And
15 there's no evidence presented on that.

16 The final point, unless there are questions on
17 this, Judge --

18 THE COURT: I take it your last point really was
19 just you can run a clinical trial and then rerun it a year
20 later with the exact same protocol dealing with the same
21 centers and you get different results.

22 MR. CARSTEN: You would get different results,
23 although assuming, we hope, that if there were statistically
24 significant results in that first clinical trial, that those
25 would be reproduced.

1 THE COURT: But even that is not a guarantee.

2 MR. CARSTEN: It's not guaranteed. And so --
3 but that's, you know, 95 percent confidence essentially,
4 right, that's the probability.

5 THE COURT: So that's the reason why -- I should
6 have ask this to Mr. Sukduang, but that's --

7 The reason why I'm sort of dubious about all the
8 inherent anticipation is none of this is leading to
9 something that you can say as a scientific matter that it's
10 going to happen. We're not in the world of hard science,
11 we're in the world of probability, statistics, and just
12 randomness.

13 So I'm pretty dubious on this. So if there's
14 something else you want to say, that would be good.

15 MR. CARSTEN: Well, I think I'm going to leave
16 that right there, Judge. I'm fine with that.

17 THE COURT: What else do you have?

18 MR. CARSTEN: The final point I've got, and I'll
19 be very, very quick about it, is written description. And
20 this pertains to Claim 9.

21 THE COURT: Right.

22 MR. CARSTEN: This is sort of a theory of the
23 case, and I think it bears in mind -- it bears to bear in
24 mind over the course of evaluating Liquidia's arguments what
25 they're trying to do is conflate INCREASE with the claim --

1 with the patent claims themselves and say, essentially,
2 they're one and the same.

3 And they're not. They are broader than INCREASE
4 and the specification is broader than INCREASE in some ways.
5 And so here is a prime example of that. And I think the
6 absolute FVC, so the same measurement, but expressed in
7 terms of the volume of the blow as opposed to the percent
8 predicted of the blow. You remember the demonstrative;
9 right?

10 THE COURT: Yes.

11 MR. CARSTEN: There was no statistical
12 significance on the trial for the ITT, the entire population
13 on that, at weeks 8 or 16.

14 THE COURT: So do the fact that there were some
15 populations for which there was statistical significance, is
16 that a relevant fact?

17 MR. CARSTEN: I don't believe so. I mean, the
18 specification at column 2 says that we may run -- in some
19 embodiments you may run trials, you may see statistical
20 significance. The inventors possess the ability to know how
21 to determine statistical significance. They understood the
22 milliliter, volume, and the percent.

23 THE COURT: In other words, your argument here
24 is in the intent-to-treat population, given that we
25 understand the predicted FVC and absolute FVC, that I think

1 it's fair to say -- tell me if I'm wrong -- absolute FVC, as
2 you know, the variables about the person and you translate
3 it according to widely understood measures into predicted
4 FVC. They're basically saying that they have the same
5 underlying concept and the predicted FVC was statistically
6 significant in the trial.

7 MR. CARSTEN: I said it and I think Dr. Wertheim
8 said it yesterday -- maybe yesterday, exactly right. I
9 mean, I think it is one blow and how you describe that is up
10 to you in terms of whether you want to follow those
11 guidelines and express it as percent then here's the
12 demographic in patient who want to express it just as a
13 volume.

14 THE COURT: And the chart as a whole, but even
15 the chart just for the total population says what to me
16 makes intuitive sense, which is to the extent you're trying
17 to study something, you do want to normalize the data. So
18 the predicted FVC has much better results than the absolute
19 FVC because if you haven't normalized the data, one group
20 could look quite a bit different than the other group in
21 terms of lung capacity.

22 MR. CARSTEN: When I saw this claim, the first
23 time the jump to mind was a picture of Shaquille O'Neal
24 sitting next to Simone Biles. And that kind of made it --
25 that clarified for me the difference between the percent

1 predicted versus the actual milliliters. We've got to
2 somehow compare those two and this is the way that
3 physicians do it.

4 With that, unless Your Honor has questions, I'd
5 like to thank the Court and thank the court staff for its
6 patience and time.

7 THE COURT: Thank you. Let me check. I have
8 one or two questions that I've written down that --

9 MR. CARSTEN: Shall I stay?

10 THE COURT: So let me check them because
11 sometimes I ask them in the course of -- because they kind
12 of come up in the course of the argument and sometimes they
13 don't or I forget or something else. So I got that one. So
14 actually you can just stand right there.

15 But, Mr. Sukduang, if you ran the INCREASE trial
16 again using the same protocol, the same centers, and the
17 same investigators but a different 320 people who meet the
18 criteria, would you get the exact same results?

19 MR. SUKDUANG: Would you get literally the same
20 numbers?

21 THE COURT: Yes.

22 MR. SUKDUANG: You couldn't and no one would say
23 you could.

24 THE COURT: Okay.

25 MR. SUKDUANG: But you'd get the same

1 magnitude -- Mr. Carsten said that when you run the INCREASE
2 trial -- and what they want to establish is that if you ran
3 the INCREASE trial again, you would get the same magnitude
4 of effect, and that's really what the FDA looks at.

5 THE COURT: Maybe you would and maybe you
6 wouldn't. That's the reason why it's -- the results are set
7 as probabilities rather than facts; right?

8 MR. SUKDUANG: Right. But in terms of if you're
9 asking this question in the context of inherency, you have
10 to go back to your claim. Your question is and we
11 believe -- and under the case law we believe that when you
12 asked Dr. Channick this, you asked me this: If you ran it,
13 would you get the exact same thing? He said no. Dr. Nathan
14 said no. And that's truthful.

15 But for inherency, the question was not whether
16 you run the INCREASE trial over and over and over again you
17 get the exact results. The question is for inherency, under
18 the law and under this claim, when you run the INCREASE
19 trial, will one or more patient necessarily and inevitably
20 get the result?

21 THE COURT: I don't think that's probably the
22 right question. In any event, you can brief that.

23 So I asked, I think, Mr. Sukduang, but I didn't
24 ask you, the correlation between BNP and NT-proBNP, as you
25 stand here right now, do you think how those two are related

1 was stated with enough -- stated in a way that I could
2 actually conclude that one is a proxy for the other?

3 MR. CARSTEN. No. I don't believe so at all,
4 Your Honor. In fact, on infringement I asked Dr. Channick
5 and he said, "I don't even measure NT-proBNP. I measure
6 BNP" as if they were different. And when it came up on his
7 direct for invalidity, he said, "Well, NT-proBNP is a
8 fragment of BNP."

9 THE COURT: That was the word.

10 MR. CARSTEN: And I don't think there was ever
11 any record evidence introduced to establish that they were
12 related in any kind of linear way or how you would say that
13 if you see an increase or decrease on one, it would
14 translate to the other. All we have is these are different
15 and they're somehow related. And I don't think that's
16 enough.

17 THE COURT: So that's something I'm interested
18 in. I think I asked Mr. Sukduang to brief it and pretty
19 much -- if I ask one of you to brief something, I'm
20 expecting both of you to brief it. But I am interested in
21 this question.

22 MR. CARSTEN: Thank you, Your Honor.

23 THE COURT: Okay. I think that's it. Let's
24 just try to wrap up one more thing and then we'll all have
25 lunch.

1 What about -- I think I told you I wanted a
2 fairly expedited schedule for briefing this. What do you
3 think in terms of -- do you have a way of dividing up when
4 these briefs would be due? I think I said I would like to
5 have them all in a month, I think.

6 MR. CARSTEN: Your Honor, we talked during the
7 break before closings and we've agreed on page limits. But
8 we have a different view in terms of the schedule.

9 THE COURT: Why don't you tell me what the page
10 limits are and see how much I agree with you.

11 MR. CARSTEN: We agreed -- like our last case,
12 we agreed on a hundred pages split between the opening and
13 the second round. And they would go first on validity and
14 we would go first on infringement.

15 THE COURT: So this hundred includes the
16 infringement and validity?

17 MR. CARSTEN: Both. And parties can split them
18 however they want.

19 THE COURT: Right, because I think infringement
20 is going to take a lot less pages than invalidity. So a
21 hundred pages altogether?

22 MR. CARSTEN: Combined.

23 THE COURT: Better. Okay. Thank you.

24 MR. CARSTEN: You have enough to read in this
25 case, Judge.

1 THE COURT: And the way it would work is you're
2 going to submit three briefs or two briefs?

3 MR. CARSTEN: We're thinking three and ten pages
4 for the reply.

5 THE COURT: That's in addition to the hundred?

6 MR. CARSTEN: 100 pages for the two and then a
7 ten-page reply.

8 THE COURT: So because you would -- a hundred
9 pages for the two is you will submit something on
10 infringement and we'll say that's 25. And then they will
11 submit something on invalidity and then your response to
12 their invalidity would be up to 75. Is that what you're
13 saying?

14 MR. CARSTEN: Yes, exactly.

15 THE COURT: That's what I allowed you all three
16 years ago?

17 MR. CARSTEN: It is.

18 THE COURT: Okay. Then ten pages for reply.
19 All right.

20 MR. CARSTEN: Then, Your Honor, we're sort of
21 hot to trot on this 52(c) issue, as you might imagine. We
22 had hoped that we might be able to convince you that we
23 could get an expedited briefing schedule and -- because
24 whether or not obviousness is going to be briefed in the
25 post-trial briefing, that would change the allocation of

1 pages dramatically.

2 What we had hoped we would be -- we would get
3 you expedited briefing on the 52(c) motion and we would say
4 that we're either going to file these documents, the first
5 round of post-trial briefing, two weeks from today or three
6 days after you issue a ruling on 52(c).

7 THE COURT: I have to tell you my reaction to
8 the 52(c) is like you want a preliminary injunction and long
9 ago that route was pursued. And I'm not really inclined to
10 be saying, okay, plaintiff says you can decide this easily,
11 Judge. Let's break it out and you have to do that first and
12 we'll see how that goes before we get on to the next thing.

13 So the only reason you're asking for it is
14 because they were on the market and that's because the court
15 in North Carolina denied your motion there, so I think
16 they're on the market. And if I rule in your favor on this,
17 it's going to be a mess regardless. So I'm not really
18 inclined to break it out and do -- so in this briefing on
19 invalidity that is to come, do you want to -- so I think to
20 the extent that you made the motion, denying that but,
21 obviously, without any prejudice to you bringing it up, so I
22 think you ought to include that -- you ought to address that
23 in your briefing in this hundred pages.

24 MR. CARSTEN: Okay.

25 THE COURT: And presumably, Mr. Sukduang, since

1 you're going first on invalidity, you probably ought to
2 address it in the opening brief; right?

3 MR. SUKDUANG: Of course.

4 THE COURT: Okay. All right. So you said the
5 schedule two weeks from now is probably -- so I think I said
6 a month today is June 26th probably. So we're talking
7 July 26th. How do you want to break this up?

8 MR. SUKDUANG: Can I ask one thing, Your Honor?
9 The Fourth of July holiday is next week and I think both
10 teams have been here nearly two weeks. I understand you
11 asked for a month. Could it be five weeks just because of
12 the holiday and everybody has been gone from their
13 respective individuals at home?

14 THE COURT: So you're appealing to my goodwill
15 as a human being here?

16 MR. SUKDUANG: You can ask any of my associates
17 that I'm like, let's burn this out. But I understand that I
18 need to be kind and I do have some personal matters I need
19 to address that I talked about before.

20 THE COURT: So instead of -- okay. One week.

21 MR. SUKDUANG: With that, Your Honor, I think
22 given, essentially, five weeks, I'm pretty sure come Monday
23 we'll be able to do a split for that and get that back to
24 you Monday or Tuesday. Given that it's five weeks, I don't
25 think there's going to be much dispute in terms of timing.

1 MR. CARSTEN: I think our proposal is two weeks,
2 two weeks, and a week.

3 THE COURT: Two weeks, two weeks, and a week and
4 two weeks starts from today. And I think I said something
5 about getting in any corrections to the transcript. I think
6 we -- so you need to do that. Today is Thursday. You need
7 to do that ASAP so you're working with the actual transcript
8 and will -- sometimes it changes page numbers, which is
9 irritating. So get them in and just in case or to save
10 effort here, when the transcript -- if the transcript
11 reflects somebody misspeaking, that's the way it goes. You
12 all misspeak. So don't try to correct it to what you wish
13 had been said.

14 But if there is -- and I'm sure there is because
15 we're all human. If there are -- and there was a lot of
16 large, complicated words being dropped that everybody was
17 having trouble with, if they're that kind of stuff, get that
18 in because -- get it in as soon as you can. Okay?

19 MR. CARSTEN: Will do. And, Your Honor, just
20 housekeeping measure, you typically like to get hyperlinked
21 materials. So can we do that maybe a week or two after?

22 THE COURT: It's got to be sooner than that.
23 While you're doing the reply brief, you can designate
24 someone to be lining up the hyperlink briefs. You can
25 hyperlink the opening briefs and answering briefs before.

1 Why don't you say the first two sets of briefs ought to be
2 in by whenever the reply brief is due.

3 MR. SUKDUANG: Hyperlink version?

4 THE COURT: Yes.

5 MR. CARSTEN: I just got a thumbs up from the
6 real person who's doing the work and she said yes.

7 THE COURT: That's the smiling woman there.

8 MR. CARSTEN: The one next to the smiling woman,
9 she's doing the work.

10 THE COURT: Now we know why she's smiling.

11 Okay. That would be good and get the reply brief
12 hyperlinked in soon thereafter, but that would be good.

13 Okay?

14 MR. SUKDUANG: On the corrections of the
15 transcripts, should we be using the dailies that you sent or
16 will there be an official transcript --

17 THE COURT: Why don't you all talk about that
18 after I'm done, all right?

19 So we're done. Thank you very much for your
20 cooperation in the actual conduct of the trial and we'll be
21 in recess.

22
23
24
25 C E R T I F I C A T E

1 I, Deanna L. Warner, a Registered Professional
2 Reporter, do hereby certify that as such Registered
3 Professional Reporter, I was present at and reported in
4 Stenotype shorthand the above and foregoing proceedings.

5
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8 Deanna L. Warner, RPR, CSR
9 Official Court Reporter
10 U.S. District Court
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